UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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MEMORANDUM, ORDER AND PARTIAL SUMMARY JUDGMENT

In re ZYPREXA PRODUCTS LIABILITY LITIGATION

04-MD-1596

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JIM HOOD, ATTORNEY GENERAL OF THE STATE OF MISSISSIPPI, ex rel. THE STATE OF MISSISSIPPI,

Plaintiff,

07-CV-645

vs.

ELI LILLY & COMPANY,

Defendant.

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JACK B. WEINSTEIN, Senior United States District Judge:

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I. Introduction

Plaintiff, the State of Mississippi, moves for partial summary judgment on its claims for compensation for its payments for the drug Zyprexa. Defendant Eli Lilly & Company ("Lilly") moves for summary judgment of dismissal. For the reasons set forth below, Lilly's motion for summary judgment is granted in part and reserved in part. Mississippi's motion for partial summary judgment is denied.

Mississippi's action is one of many thousands of cases relating to Lilly's drug Zyprexa, one of a number of "atypical" or "second-generation" antipsychotic drugs to come on the market over the past twenty years. Second-generation antipsychotics were perceived of as more effective than predecessor drugs for treating serious psychiatric disorders, such as schizophrenia and bipolar disorder. They have been widely prescribed for these and a variety of other mental conditions. Zyprexa has been used by large numbers of people, resulting in tens of billions of dollars in total sales for Lilly.

Zyprexa is widely believed to be one of the most efficacious of the second-generation antipsychotics. *See* Benedict Carey, *Study Finds Little Advantage in New Schizophrenia Drugs*, N.Y. Times, Sept. 20, 2005, at F1 ("One of the newer [atypical antipsychotic] drugs, Zyprexa, from Eli Lilly, helped more patients control symptoms for significantly longer than the other drugs. . . . The patients on Zyprexa were less likely to be hospitalized because their condition worsened than those taking the other drugs . . . ."). As the court has previously observed: "There is little doubt about the usefulness of Zyprexa for both on-label and some off-label purposes. It assists many people with serious debilitating diseases. It has substantially increased the quality of life of many thousands of people. . . . Many treating physicians continue to rely on

it after what is by now extensive revelation of information about Zyprexa's risks and benefits." *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 575 (E.D.N.Y. 2007); *see also In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 77 (E.D.N.Y. 2008).

In the case of some users who were leading dismal, hazardous lives as a result of their mental problems, Zyprexa has enabled a greatly improved quality of life. Large numbers of such patients have been litigants in this court. *See, e.g., Belcher v. Eli Lilly & Co.*, No. 06-CV-2782, 2009 WL 3597447 at *9 (E.D.N.Y. Oct. 16, 2009) ("During an October 1999 hospitalization, Ms. Belcher initially required restraints to control her aggressive behavior; once Zyprexa was administered, she 'started responding to the treatment and became calmer and more directable.' In October 2001, after discontinuing use of Seroquel, Ms. Belcher continued to receive Zyprexa and enjoyed 'better control of her psychotic symptoms.'" (internal citations omitted)); *Folse v. Eli Lilly & Co.*, No. 04-CV-1612, 2009 WL 3596526 at *9 (E.D.N.Y. Oct. 16, 2009) ("Mr. Folse had previously tried and failed to find relief from several psychiatric medications for his anxiety and depression, including Zoloft, Paxil, Effexor, Buspar, and Remeron. . . . Mr. Folse responded well to Zyprexa. His symptoms improved. When Mr. Folse returned for his second visit with Dr. Concepcion on February 7, 2002, Mr. Folse displayed noticeable improvements while taking his medications. Dr. Concepcion noted that Mr. Folse's 'mind [was] resting better at night' and he was 'not as hyper during the day.' . . . By his third visit with Dr. Concepcion in March 2002, Mr. Folse was 'doing good' with 'no physical complaints'; his 'stress level, mood and anxiety [had] been more manageable.'" (internal citations omitted; alterations in original)).

Notwithstanding Zyprexa's benefits, two circumstances have resulted in a flood of Zyprexa-related litigation, of which Mississippi's suit is a part. First, Lilly allegedly improperly

promoted Zyprexa for use in treating conditions for which it was never approved by the federal Food and Drug Administration ("FDA"). Second, Zyprexa is associated with serious metabolic side-effects, including weight gain and diabetes, for which Lilly allegedly provided inadequate warnings to patients, physicians, and payors such as the State of Mississippi.

Related civil and criminal actions have been filed in federal and state courts by the federal government, state attorneys general, insurance companies and other third-party payor institutions, and individual plaintiffs. Institutional and individual plaintiffs number in the tens of thousands. The resulting complex, sprawling series of Zyprexa litigations in state and federal courts has involved federal administrative agencies, federal criminal charges, federal and state statutory claims brought by the federal government and the states' attorneys general, the common laws of all fifty states, a huge national discovery archive, and the utilization of six special masters, two plaintiffs' steering committees, a national class action with a class of more than 30,000 third-party payors (now on appeal), individual claims for physical injuries (more than 30,000 of which have been settled), a derivative action against Lilly's Board of Directors, and liens and "hold-backs" on individual recoveries by the states and the federal government and independent distribution entities.

Mississippi's suit is one of a series of claims asserted by the attorneys general of more than forty states. Total recovery claimed by Mississippi is in the billions of dollars.

With the assistance of a Special Settlement Master appointed by this court, all similar claims by other states pending before this court have been tentatively or conclusively settled, as have the claims of all but two states brought in state courts. The Settlement Master reports that

the amounts for each settled state attorney general claim falls within reasonable parameters of tens of millions of dollars.

Mississippi asserts claims under (1) the Mississippi Medicaid Fraud Control Act (MFCA), (2) the Mississippi Products Liability Act (PLA), (3) the Mississippi Consumer Protection Act (CPA), and (4) common law theories of fraud, unjust enrichment, negligence, and gross negligence. The crux of these claims is that Lilly improperly promoted Zyprexa for unapproved and "non-medically necessary" uses and failed to adequately warn about the drug's adverse side-effects.

Statutory penalties and monetary damages are sought. Arguing that Zyprexa's price was artificially inflated by Lilly's improper promotions, the State seeks to recover the difference between Zyprexa's market price and the value actually received by patients over an eleven-year period. It also seeks to recover the costs of treating Medicaid recipients whose diabetes and other diseases are attributable to Zyprexa. Statutory penalties are claimed in connection with each of an estimated nearly one million sales of Zyprexa on prescriptions written for Mississippi residents since the drug was first sold in late 1996, as well as specifically in connection with every Medicaid payment made for "non-medically necessary" uses of Zyprexa.

Crucial to Mississippi's claims is statistical evidence relating to the population of patients who received Zyprexa in Mississippi. The State relies on expert analyses to establish the amount by which Lilly's improper promotions inflated the price of Zyprexa, the amounts by which the State Medicaid program overpaid for Zyprexa, the number of additional Zyprexa prescriptions that are attributable to Lilly's alleged promotional misconduct, and the costs to the State Medicaid program of treating diseases caused by Zyprexa. Relevant to the appropriateness of

this evidence are numerous ruling appellate decisions which have placed narrow limits on the use of aggregate evidence in mass tort cases. Also relevant is the decision on aggregate proof and statistical evidence in connection with a national class action brought by insurance companies and other third-party payors that paid for Zyprexa (the "Third-Party Payors"). *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69 (E.D.N.Y. 2008). In the Third-Party Payors case the court certified the class and approved the limited use of statistical evidence in support of plaintiffs' claims. An appeal of that certification decision is now pending before the Court of Appeals for the Second Circuit.

Mississippi brings suit individually, rather than as a Rule 23 class action or a quasi-class action. In this respect, decisions in class actions concerning the use of statistical or aggregate evidence are not directly on point. In effect, however, Mississippi's individual claim is structured on the foundation of many thousands of conceptually separate claims associated with individual patients, coordinated and aggregated by the State for purposes of recovering a portion of its overall Zyprexa-related Medicaid costs. Such a "structural" class action is congruent with other forms of aggregate litigation insofar as the State seeks to use generalized evidence to prove its claims. The extensive case law regarding the uses and limitations of aggregate evidence in class and other mass actions is applicable. *See* Part IV.E.1, *infra.*

Mississippi relies on substantially identical expert analyses by several of the same experts offered by the Third-Party Payors. The State's claims may survive summary judgment only insofar as they are premised on the difference between Zyprexa's price and the value actually received by patients, based upon theories and forms of aggregate evidence similar to those approved in the Third-Party Payors litigation. To the extent that Mississippi's claims may

survive summary judgment on this ground, decision on Lilly's motion is reserved pending the outcome of the appeal of the Third-Party Payors certification decision.

In all other respects Lilly's motion for summary judgment is granted, because the use of aggregate proof to establish essential elements of Mississippi's theories of recovery is barred by applicable case law.

The State's motion for partial summary judgment is denied. Proceedings in this action are stayed pending the outcome of appellate review of the Third-Party Payors certification decision.

II. Zyprexa Adjudications

Litigation against Lilly for injuries allegedly caused by Zyprexa was initiated in this court in March 2004. *See Benjamin v. Eli Lilly & Co.*, No. 04-CV-893 (E.D.N.Y. filed March 3, 2004). Thousands of cases were then transferred here from federal district courts throughout the United States pursuant to an order of the Judicial Panel on Multidistrict Litigation ("MDL"). *See* Letter from Multidistrict Litigation Panel to Clerk of the Eastern District of New York, *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, Docket Entry No. 1 (E.D.N.Y. Apr. 14, 2004). Similar cases have been litigated in state courts, *see In re Zyprexa Prods. Liab. Litig.*, 239 F.R.D. 316 (E.D.N.Y. 2007) (Communication to State Judges on Cooperation Between Federal and State Judges); many of them were removed to federal courts and then transferred to this court.

Cooperation between federal and state courts has been encouraged at all stages of the *Zyprexa* litigation. *See, e.g.*, *In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 262 (E.D.N.Y. 2006) ("Cooperation with state courts will continue to be stressed."); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 898105, at *1 (E.D.N.Y. Apr. 6, 2006)

("Coordination and cooperation between state and federal courts has been encouraged."); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 197151 (E.D.N.Y. Jan. 26, 2006) (letter to state judges with Zyprexa cases suggesting coordination and cooperation); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2004 WL 3520248, at *4 (E.D.N.Y. Aug. 18, 2004) (directing defendant Lilly and Plaintiffs' Steering Committee I to "confer regarding procedures for coordination of state-court discovery with discovery in this [multidistrict litigation]").

A. Administrative Controls

Zyprexa has been subject to supervision by the FDA since it was first developed. It was initially approved by the FDA in 1996 only for treatment of short-term manifestations of psychotic disorders. *See* Part III.B, *infra*. In 2000, the FDA expanded the indications for which Zyprexa was approved to other uses in connection with bipolar disorder and schizophrenia. *See id.*

Since Zyprexa's initial FDA approval, the FDA has several times investigated the risks and side-effects associated with this drug and other atypical antipsychotics; changes to Zyprexa's warning label have been ordered and made. *See generally* Part III.E.1, *infra*. In 2000, the FDA requested information from Lilly concerning Zyprexa's relation to diabetes and hyperglycemia. *See id.* In 2003, the FDA imposed on all atypical antipsychotics, including Zyprexa, a required warning relating to hyperglycemia and diabetes mellitus. *See id.* In 2004, the FDA requested that Lilly send a "Dear Doctor" letter to physicians informing them of the new 2003 warning. *See id.* In 2007, the FDA raised further concerns about Zyprexa's warning label in a letter to Lilly. *See* Part III.E.3, *supra*.

B. Private Plaintiff Litigation

Some 30,000 cases have been brought against Lilly by individual plaintiffs suffering from serious psychiatric problems who were treated with the Zyprexa. They principally allege that Zyprexa caused deleterious side effects of excessive weight gain, hyperglycemia, and diabetes; that Lilly misled them and their physicians about the likelihood of these side effects; and that, had they or their attending physicians been aware of the risks, they would not have used Zyprexa or would have taken measures to address its adverse effects.

The individual Zyprexa user litigation has been administered as a quasi-class action. *See In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 262 (E.D.N.Y. 2006) ("The court, magistrate judge and special masters will continue to administer this litigation as a quasi-class action."); *In re Zyprexa Prods. Liab. Litig.*, 451 F. Supp. 2d 458, 477 (E.D.N.Y. 2006) ("Recognizing its obligation to exercise careful oversight of this national 'quasi-class action,' the court has already utilized its equitable power to limit attorneys' fees and costs.") (citation omitted); *In re Zyprexa Prods. Liab. Litig.*, 433 F. Supp. 2d 268, 271 (E.D.N.Y. 2006) (finding that individual Zyprexa user litigation "may be characterized properly as a quasi-class action subject to the general equitable power of the court"); *In re Zyprexa Prods. Liab. Litig.*, 424 F. Supp. 2d 488, 491 (E.D.N.Y. 2006) (same); *In re Zyprexa Prods. Liab. Litig.*, 233 F.R.D. 122, 122 (E.D.N.Y. 2006) (same).

On April 16, 2004, a class action was filed on behalf of individuals claiming personal injury based on, among other claims, Lilly's failure to provide an adequate warning about the risks of Zyprexa. *See Ortiz v. Eli Lilly & Company*, No. 04-CV-1587 (E.D.N.Y.). A second and substantially similar class action was filed in this court on May 19, 2004. *See Tringali v. Eli*

Lilly & Company, No. 04-CV-2104 (E.D.N.Y.). On September 15, 2004, Lilly and plaintiffs' counsel in the two putative class actions entered into an agreement to execute stipulations of dismissal. *See* Joint Memorandum of the Parties Regarding Stipulation of Voluntary Dismissal of Certain Claims, *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, Docket Entry No. 80-2 (E.D.N.Y. Sept. 15, 2004).

Discovery and negotiations in the first batch of settled individual cases were overseen in part by a court-appointed special discovery master and four special settlement masters. In November 2005, Lilly, without conceding liability, entered into a settlement covering some 8,000 individual plaintiffs. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2005 WL 3117302 (E.D.N.Y. Nov. 22, 2005). The settlement resolved virtually all cases then pending in the multidistrict litigation, along with some state cases. *See id.*

An attorneys' fee structure for the individual cases was ordered, capping fees at 20% of recovery in smaller, lump-sum claims, and at 35% of recovery in other claims. *See In re Zyprexa Prods. Liab. Litig.*, 424 F. Supp. 2d 488 (E.D.N.Y. 2006). Costs related to the individual cases and charged to individual settling plaintiffs were limited. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 2443248 (E.D.N.Y. Aug. 24, 2006). Counsel for some 2,000 individual plaintiffs filed an appeal of an order capping fees, *see In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2007 WL 2340789 (E.D.N.Y. Aug. 17, 2007), which is now pending before the Court of Appeals for the Second Circuit. The magistrate judge allocated funds from a first common benefit fund after reviewing the first Plaintiffs' Steering Committee's ("PSC I") applications. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2007 WL 805793 (E.D.N.Y. Mar. 15, 2007). Payments have been substantially completed for PSC I.

Following an influx of thousands of new cases, after January 2007 the parties announced another round of settlements, which are nearing completion. A second common benefit fund was established to compensate members of a second PSC for their work. *See In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d at 262.

A national system for resolving Medicare and Medicaid liens and "hold-backs" in connection with individual Zyprexa recoveries was approved. *See In re Zyprexa Prods. Liab. Litig.*, 451 F. Supp. 2d 458 (E.D.N.Y. 2006). All states and the federal government agreed to modify their lien demands to provide a national equitable system. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 3501263, at *1 (E.D.N.Y. Dec. 4, 2006) ("In compliance with this court's instructions . . . all fifty states as well as the federal government have resolved their Medicare and Medicaid liens.") (citation omitted). As a result of the global settlement of these ancillary claims, a total of $21,100,849.60 has been allocated to the states and $22,342,445.37 to the federal government, reflecting their shares of compensation received from Lilly by individual plaintiffs, whose recovery for their own injuries from Zyprexa included recovery of amounts originally paid by Medicaid and other "welfare" programs. *See* Administrator's Report of Aug. 28, 2009, *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596 (E.D.N.Y.) (filed under seal). The State of Mississippi has recovered $755,496.32 through this global lien and hold-back settlement. *Id.*

A class action has been brought on behalf of third-party payor institutional plaintiffs, including pension funds, labor unions, and insurance companies that cover their members' health benefits; they have made outlays for Zyprexa prescriptions. Mail fraud under the Racketeer Influenced and Corrupt Organizations Act ("RICO") is alleged, *see* 18 U.S.C. § 1964, predicated

on overpricing supported by excessive claims of utility as well as disavowal of adverse secondary effects of the drug, primarily weight gain and diabetes. That class has been certified. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 201 (E.D.N.Y. 2008). The certification decision is currently on appeal before the Court of Appeals for the Second Circuit.

Individual plaintiffs who bought, or paid a portion of the purchase price for, Zyprexa for their own use also sought class action status on a similar theory. Certification of this individual payor class action was denied. *See id.* at 201-02.

Some of Lilly's shareholders have filed suit because of the decline in share price. *See In re Eli Lilly & Co. Sec. Litig.*, No. 07-CV-1310 (E.D.N.Y.). This litigation has been dismissed on statute of limitations grounds. *See In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496 (E.D.N.Y. 2008).

Current shareholders have sued in this court in the form of three separate shareholder derivative actions. *See Waldman v. Taurel*, No. 08-CV-560 (E.D.N.Y.); *City of Taylor Employees Retirement System v. Taurel*, No. 08-CV-1554 (E.D.N.Y.); *Robins v. Taurel*, No. 08-CV-1471 (E.D.N.Y.). Similar cases are pending in other courts. Settlement negotiations are ongoing.

Additional cases transferred as part of the multidistrict litigation or commenced in this district are being managed by a special master, who is tracking settlements, setting timelines for discovery and the adjudication of dispositive motions, and scheduling trial dates. *See* Case Management Order No. 32, *In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596, Docket Entry No. 2072 (E.D.N.Y. Mar. 3, 2009). Individual actions originating in the Eastern District of New York have been placed on an expedited discovery and motion schedule so that trial on those

actions may, if necessary, move forward without undue delay. Many cases originally set for trial in this court have been settled or withdrawn.

The court has ruled on the parties' *Daubert* motions challenging proposed expert testimony in a number of cases. *See, e.g., In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596, 2009 WL 1357236 (E.D.N.Y. May 12, 2009) (ordering the exclusion of plaintiffs' proposed expert testimony in twenty cases); *see In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596, 2009 WL 1322286 (E.D.N.Y. May 12, 2009) (approving plaintiffs' proposed expert testimony in two cases); *In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596, 2009 WL 1322292 (E.D.N.Y. May 12, 2009) (approving defendant's proposed expert testimony); *Souther*, 489 F. Supp. 2d at 281-91 (denying plaintiffs' and defendant's *Daubert* motions to exclude expert testimony).

A series of summary judgment motions by Lilly in individual Zyprexa user actions have been decided and others are pending. *See, e.g., Souther, et al. v. Eli Lilly & Co.*, 489 F. Supp. 2d 230 (E.D.N.Y. 2007). In the most recent series of motions, summary judgment has been granted against individual plaintiffs. *See, e.g., Eric Fuller v. Eli Lilly & Co.*, No. 06-CV-2782, 2009 WL 2485829 (E.D.N.Y. July 31, 2009). Several individual plaintiffs have appealed the grant of summary judgment. Review of those cases is pending before the Court of Appeals for the Second Circuit. Summary judgment has been denied with respect to other individual plaintiffs. *See Arlene Earl v. Eli Lilly & Co.*, --- F.Supp.2d ---, No. 07-CV-3912, 2009 WL 2762170 (E.D.N.Y. Aug. 28, 2009), *mot. for recons. denied*, Docket Entry No. 27 (E.D.N.Y. Oct. 14, 2009); *Venica Pruett v. Eli Lilly & Co.*, No. 07-CV-1931, 2009 WL 2245068 (E.D.N.Y. July 22, 2009).

Substantial numbers of individual plaintiffs' Zyprexa actions continue to be filed in this court and elsewhere.

C. Federal Criminal and Civil Actions and State Attorney General Civil Actions

The federal government sought criminal and civil penalties against Lilly in connection with "off-label" promotion of Zyprexa—*i.e.*, promotion of Zyprexa for uses that were not approved by the FDA. Many state attorneys general sued on behalf of their states' citizens seeking various state-law remedies as well as reimbursement for payments for Zyprexa made with state and federal funds via state Medicaid and other programs. Some forty-two states and the federal government have settled independent claims with Lilly. Three state actions are still pending, including Mississippi's, the only one still pending in this court.

1. Federal Criminal and Civil Settlement with Penalties and Provision for State Payments

In January 2009 Lilly pled guilty in the Eastern District of Pennsylvania to federal criminal charges of introducing misbranded drugs into interstate commerce in connection with its promotion of Zyprexa for off-label uses. Upon the plea of guilty, a $615 million criminal fine was imposed. *See* Memo. in Supp. of Pl.'s Mot. for Partial Summ. J., Sept. 18, 2009, Ex. 3 (Guilty Plea Agreement, Jan. 14, 2009); *see also* Eli Lilly & Company, Press Release, Lilly Resolves Investigations of Past Zyprexa Marketing and Promotional Practices, Jan. 15, 2009, *available at* http://newsroom.lilly.com/releasedetail.cfm?ReleaseID=359242.

Simultaneously with its guilty plea, Lilly settled civil claims with the federal government. *Id.* Lilly's settlement payments included both a $438 million federal government share and a $362 million state share set aside and designed to compensate settling states for amounts paid out

of state funds for Zyprexa. *Id.* States, like Mississippi, that opted to independently pursue their claims against Lilly did not receive a portion of this state share.

In connection with the federal civil settlement, Lilly also entered into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. *Id.* The agreement requires Lilly "to maintain its compliance program and to undertake a set of defined corporate integrity obligations for five years" and "provide[s] for an independent third-party review organization to assess and report on the company's systems, processes, policies, procedures and practices." *Id.* Independent state settlements contain equivalent obligations by Lilly to improve its ethical practices. *See* Part II.C.2.a, *infra.*

2. State Attorney General Civil Actions

a) Settlements

In March 2008, Lilly settled with the State of Alaska during a trial on Zyprexa-related claims. *See* Alex Berenson, *Alaska Suit Against Lilly Is Settled*, N.Y. Times, Mar. 27, 2008, at C1. That State's lawsuit sought reimbursement for the medical costs of Alaska Medicaid patients who developed diabetes while taking Zyprexa; the State's claim to recover costs associated with Lilly's off-label promotion of Zyprexa was dismissed before trial. *See* Alex Berenson, *Lilly Executive Discussed Off-Label Uses for Drug*, N.Y. Times, Mar. 15, 2008, at C1. Some of the materials introduced in that trial are available as part of the public record.

Other state settlements have followed. In October 2008, thirty-two states and the District of Columbia settled claims relating to improper off-label promotion of Zyprexa. *See* Alex Berenson, *33 States to Get $62 Million in Zyprexa Case Settlement*, N.Y. Times, Oct. 7, 2008, at B7. The settling states were: Alabama, Arizona, California, Delaware, Florida, Hawaii, Illinois,

Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington and Wisconsin, as well as the District of Columbia. *See* Eli Lilly & Company, Press Release, Eli Lilly and Company Resolves Investigation Involving Numerous States, Oct. 7, 2007, *available at* http://newsroom.lilly.com/releasedetail.cfm?ReleaseID=338857.

In connection with the October 2008 state settlements, Lilly agreed to be bound by compliance provisions relating "to the company's promotional practices, dissemination of medical information, funding of continuing medical education (CME) and grants related to Zyprexa, and continued disclosure of Zyprexa clinical trials and their results." *Id.* Lilly also agreed to "provide signatory attorneys general with information related to compensation made to healthcare professionals who have received more than $100 annually from the company for promotional speaking or consulting regarding Zyprexa in the U.S." *Id.*

State attorney general actions on behalf of the citizens of Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, and West Virginia were brought in this court, or transferred to this court pursuant to an order of the Judicial Panel on Multidistrict Litigation. The state Attorneys General of Arkansas, Pennsylvania, South Carolina, and Utah brought suit in their respective state courts. A putative *qui tam* action by a whistleblower representing California was dismissed. Order, *California ex rel. Jaydeen Vincente v. Eli Lilly & Co.*, No. 08-CV-600, Docket Entry No. 84 (E.D.N.Y. Apr. 23, 2008).

Most state attorney general cases have been settled. In addition to the thirty-two state settlements in October 2008 and the state of Alaska's settlement, settlements have been

tentatively reached or concluded by Connecticut, Idaho, Louisiana, Minnesota, Montana, New Mexico, South Carolina, Utah, and West Virginia. The final settlement agreements contain compliance provisions mirroring those of the October 2008 state settlements, covering Lilly's promotional activities, dissemination of medical information, use of continuing medical education and grants, payments to consultants and speakers, use of product samples, and clinical research. *See, e.g.,* Final Judgment and Consent Decree, *Connecticut v. Eli Lilly & Co.*, No. 08-CV-955, Docket Entry No. 247 (E.D.N.Y. Sept. 29, 2009). Special Settlement Master Michael Rozen reported to the court that the settlement amounts agreed by these nine states are in rough equivalency, relative to the size of each state. *See* Sept. 21, 2009 Hr'g Tr. at 9, *In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596 (E.D.N.Y).

b) Mississippi

Mississippi's case is the last open state attorney general case before this court. Arkansas and Pennsylvania are the only other state attorney general cases still pending, both in state courts.

Because Mississippi, like eleven other states, elected to continue pursuing its claims against Lilly, it did not participate in the recovery obtained by thirty-two states in the October 2008 settlements, and did not receive a portion of the state share provided for in the federal civil settlement. *See* Parts II.C.1 to 2.a, *supra.*

Other litigants' settlements in the related Zyprexa litigations described above have directly and indirectly affected Mississippi. First, as already noted, Mississippi has directly recovered $755,496.32 for liens and "hold-backs" as its share of compensation received from Lilly by individual plaintiffs whose recovery for their own injuries from Zyprexa included

amounts paid by the states through Medicaid and other "welfare" programs. *See, e.g.*, Administrator's Report of Aug. 28, 2009, *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596 (E.D.N.Y.) (filed under seal); Part II.B, *supra*.

Second, the extensive ongoing compliance provisions to which Lilly has agreed in its settlements of claims by the federal government and the other states are not subject to any geographic limitation. Mississippi is thus indirectly protected by these provisions, though it lacks any right to enforce them directly. As discussed above, Lilly is subject to compliance provisions in the October 2008 state settlement agreements, the corporate integrity agreement entered into in connection with the federal civil settlement, and the final settlement agreements of states that pursued claims in federal or state court. *See* Parts II.C.1 to 2.a, *supra*. These agreements contain terms that relate to the company's promotional practices, dissemination of medical information, funding of continuing medical education and grants related to Zyprexa, and continued disclosure of Zyprexa clinical trials and their results. *See* Part II.C.2.a, *supra*. Other terms require Lilly to provide information related to compensation made to healthcare professionals for promotional speaking or consulting regarding Zyprexa, to maintain a compliance program and undertake a set of defined corporate integrity obligations, and to provide for an independent third-party review organization to assess and report on the company's procedures and practices. *See* Parts II.C.1 to 2.a, *supra*.

III. Facts

A. Zyprexa and Anti-Psychotic Medications

This court has previously detailed the history of the development and merchandizing of Zyprexa and similar antipsychotic medications. It is repeated here for the reader's convenience.

Lilly's prescription medicine Zyprexa, with a chemical name of olanzapine, is one of a class of medications known as "atypical" or "second-generation" antipsychotics ("SGAs") that treat schizophrenia and bipolar disease. Schizophrenia is a severe, debilitating mental illness that afflicts over one percent of the general population—2.5 million Americans—often beginning in late adolescence or early adulthood. *See* Robert Freedman, *Schizophrenia,* 349(18) New Eng. J. Med. 1738, 1738 (2003); Gary D. Tollefson & Cindy C. Taylor, *Olanzapine: Preclinical and Clinical Profiles of a Novel Antipsychotic Agent,* 6(4) CNS Drug Reviews 303, 304 (2000); U.S. Dep't of Health & Human Servs., Mental Health: A Report of the Surgeon General 273 (1999), http://www.mentalhealth.org/features/surgeongeneralreport/home.asp; [American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders at 308, 4th ed., Washington DC, American Psychiatric Press Inc., 2000 ("DSM-IV-TR")]. One of the most complex and challenging of psychiatric disorders, schizophrenia is a heterogeneous syndrome of disorganized and bizarre thoughts, delusions, hallucinations, inappropriate affect, and impaired psycho-social functioning. *See* DSM-IV-TR, *supra* at 298-302. The illness occurs when a patient suffers two or more of the following characteristic symptoms: (1) delusions, (2) hallucinations, (3) disorganized speech, (4) grossly disorganized or catatonic behavior, and (5) negative symptoms, *see id.,* or has bizarre delusions or hallucinations of voices commenting on the person's behavior or thoughts. Research has shown a variety of abnormalities in schizophrenic brain structure and function. Pharmacotherapy: A Pathophysiologic Approach (Joseph T. Dipiro et al., eds., 5th ed. 2002) (hereinafter "Pharmacotherapy") at 1219; *see* DSM-IV-TR, *supra* at 299. Causation is believed to be multi-factorial. Pharmacotherapy, *supra* at 121; *see* DSM-IV-TR, *supra* at 305-06, 309-11.

Bipolar disorder is a serious, lifelong mental illness marked by dramatic shifts in mood, from abnormally elevated, expansive, or irritable moods to states of extreme sadness and hopelessness, often with periods of normal mood in between. Nat'l Inst. of Mental Health, Bipolar Disorder, *available at* http://www.nimh.nih.gov/publicat/bipolar.cfm (last visited June 30, 2008); *see* Decl.

of Steven Klotz, M.D. 2, Feb. 22, 2007, Docket Entry No. 99 ("Klotz Decl."). Bipolar I, characterized by the occurrence of one or more manic episodes or mixed episodes, often with major depressive episodes, and Bipolar II, characterized by one or more major depressive episodes accompanied by at least one hypomanic episode, are separate disease states. *See* DSM-IV-TR, *supra* at 382-92. Because of its complexity, bipolar disease can be difficult to diagnose; between seven and ten years of mis-diagnoses and incorrect treatment is typical for bipolar patients. Klotz Decl. 6. "[U]ntreated bipolar disorder can be disastrous; 10 percent of sufferers commit suicide." Mary Carmichael, *Welcome to Max's World,* Newsweek, May 26, 2008.

In the past five years there has been extensive research into diagnosing and recommending treatments for bipolar disorder, funded in part by pharmaceutical manufacturers. Klotz Decl. 3. There has been a corresponding growth of bipolar diagnoses—correct *and* incorrect—leading to an increase in patients and greater awareness of the disease; many patients labeled "bipolar" are mentally ill but, upon detailed psychiatric examination, not bipolar. *Id.* at 3-4. An estimated 5.7 million Americans are affected by the disorder.

Both schizophrenia and bipolar disorder, like many mental illnesses, display considerable biological and symptomatic differences. *See* Decl. of Richard G. Frank, Ph.D. at ¶ 7, Jan. 8, 2008, Docket Entry No. 148 ("Frank Decl."). Often, patients with these disorders have other psychiatric and physical problems. *Id.* Due to the illnesses' heterogeneity, different people respond differently to different psychotropic drugs. Which drug will work best for a new patient is often unknown until he or she tries it; thus clinical decision-making about psychotropic medications almost inevitably is based on "trial and error." *Id.* at 3-4 (citing H.A. Huskamp, *Managing Psychotropic Drug Costs: Will Formularies Work?,* Health Affairs 22(5): 84-96 (2003)). As a result, third-party payors prefer not to place strong restrictions on the use of antipsychotic medications. *Id.* at 4.

While the two primary uses of second-generation antipsychotics remain the treatment of schizophrenia and bipolar disorder, antipsychotics are prescribed off-label, i.e., for non-FDA

approved purposes, to treat symptoms related to agitation, anxiety, psychotic episodes, obsessive behavior, behaviors related to dementia, depression, obsessive compulsive disorder ("OCD"), Post Traumatic Stress Disorder ("PTSD"), personality disorders, and Tourette's Syndrome. *See* Frank Decl. at 3 (citing Agency of Health Research and Quality, Off Label Use of Atypical Antipsychotic Drugs, *available at* http://effectivehealthcare.ahrq.gov/reports/topic.cfm?topic=8&sid=34&rType=10). "'Off-Label' prescriptions are a mainstay of the drug industry—an estimated 21% of drug use overall." Anna Wilde Mathews & Avery Johnson, *FDA to Propose Guidelines for 'Off-Label' Drug Use,* Wall St. J., Feb. 15, 2008; *see* [Decl. of Meredith Rosenthal at 26, Feb. 27, 2007, Docket Entry No. 101 ("Rosenthal Decl.")] (noting that Zyprexa's "unapproved uses represent an average of 31% of Zyprexa mentions in the National Disease and Therapeutic Index (NDTI) database."). Examples of off-label use include using a drug to treat a condition for which it is not indicated, treating an indicated condition with different doses than those specified on the label, and prescribing a drug for a different patient population than that indicated (such as children, if it has only been approved to treat adults). Off-label uses of approved medications have not been subjected to the baseline FDA scrutiny required for on-label indications, and are thus considered riskier. *See id.* at 1021.

Two common off-label uses of SGAs are for dementia in the elderly and children with bipolar disorder. One in four nursing home residents take antipsychotic drugs, with sales in 2007 totaling over $13 billion. Kris Hundley, *Dementia Relief, with a Huge Side Effect: The Off-Label Use of Some Drugs Is Helping,* Tampa Bay Times, Nov. 18, 2007. "The use of antipsychotic drugs to tamp down the agitation, combative behavior and outbursts of dementia patients has soared, especially in the elderly." [Laurie Tarkan, *Doctors Say Medication Is Overused in Dementia*, N.Y. Times, June 24, 2008, at F1.]. Use of the medications [is] particularly high in nursing homes. Sedatives and antipsychotics—despite their potentially severe side effects, including increased risk of death—present a tempting option to overextended staff. *Id.* Of Zyprexa's $4.4 billion sales in 2006, 26.6% were to patients over 64. *Id.*

Off-label use of antipsychotics in children with bipolar disorder is a recent phenomenon. "Between 1994 and 2003, the number of children treated for bipolar disorder in the United States increased to more than 800,000 from 20,000." M. Alexander Otto, *Should Kids Get These Drugs? Plan Likely to Increase Scrutiny of Anti-Psychotics in Children,* News Tribune, May 12, 2008. At least some of those were diagnosed "no doubt . . . wrongly. The disease is hard to pin down." *See* Carmichael, *supra.* Just two SGAs have been approved for use by children, Risperdal and Abilify; Zyprexa is indicated for use by adults only.

A. First-Generation or "Typical" Anti-Psychotics ("FGAs")

Zyprexa is generally known as a "second-generation antipsychotic" or "SGA" to differentiate it from older, first-generation antipsychotics ("FGAs"), which were the standard drug therapy for schizophrenia until the 1990s. FGAs include chlorpromazine (Thorazine), fluphenzine (Proxilin), haloperidol (Haldol), molindone (Moban), thioridazine (Mellaril), loxapine (Loxitane), mesoridazine (Serentil), perphenazine (Trilafon), thiothixene (Navane), and trifluoperazine (Stelazine), some of which have been in use since the 1950s. Pharmacotherapy, *supra,* at 1224. FGAs are sometimes referred to as "typical" antipsychotics and SGAs as "atypical."

Although many different FGAs exist, they share similar levels of efficacy. They are, generally speaking, post-synaptic dopamine-receptor antagonists, i.e., they target dopamine receptors in the brain. *Id.* at 1220. A troubling side effect of typical antipsychotics is that the blockage of dopaminergic neurotransmission causes extrapyramidal syndromes ("EPS") such as Parkinsonian effects or tremors. *Id.* at 1223. Tardive Dyskinesia ("TD"), a long-lasting movement disorder, frequently occurs with prolonged treatment. *Id.*

B. Second-Generation or "Atypical" Anti-Psychotics ("SGAs")

Because of FGAs' potential for severe side effects and their limited efficacy, many pharmaceutical companies searched for new

drugs that would be more effective and cause less movement disorder. By the 1980s, clozapine, the first SGA, was being investigated on that hypothesis. Since it had an "atypical index" when measuring its effect on different parts of the brain, clozapine became known [as] an "atypical" antipsychotic. 2007 Physicians Desk Reference at 2184-89. Clozapine has different effects than FGAs on areas of the brain that control movement; it was hoped that it would cause less movement disorder than other antipsychotics. *Id.* While clozapine turned out to be effective, its toxic side effects, including agranulocytosis (dramatic loss of white blood cells), limited its use to about ten percent of persons with schizophrenia. *Id.;* [Rosenthal Decl. at 6]. Although clozapine was the first atypical antipsychotic, it tends to stand on its own between FGAs and SGAs. Clozapine was approved by the FDA in September 1989 and was the only SGA available in the United States until 1993, although its potential toxicity assured only a small market share. *Id.* at 5.

During the 1990s pharmaceutical companies, building on the "atypical" hypothesis, developed newer, second-generation antipsychotic drugs ("SGAs") attempting to capture the enhanced therapeutic effect of clozapine without its toxicity and [ ] the side effects caused by traditional antipsychotics, such as EPS and TD. "The introduction of atypical antipsychotic medications was trumpeted by the manufacturers of these pharmaceutical agents as a major advance in the treatment of schizophrenia with improved symptomatic control of the psychosis and a reduction in both tardive dyskinesia and extra pyramidal side effects." [Decl. of William Wirshing, M.D. at 7, Jan. 31, 2007].

In late 1993, risperidone became the first non-clozapine SGA to receive Food and Drug Administration ("FDA") approval. In early 1994, Janssen, a subsidiary of Johnson & Johnson, began marketing and selling risperidone under the brand name Risperdal. During the next two years, Janssen heavily marketed and promoted Risperdal for its approved indication, management of the manifestation of psychotic disorders, and, allegedly, for multiple non-approved uses, including attention deficit-hyperactivity disorder, bipolar disorder, and aggression associated with late-onset dementia. By late 1996, Janssen had a significant share of

the United States antipsychotic drug market, and had demonstrated the sales potential of marketing SGAs for non-approved indications. When Zyprexa entered the market in 1996, Risperdal was seen as its primary competitor. *See* Strategy Integration Team, Eli Lilly & Co., Zyprexa in Serious Mental Illness (65 Plus Years)—A Strategy Review (undated).

The FDA first approved Zyprexa on September 30, 1996, for use in treating "the manifestations of psychotic disorders" seen in schizophrenia. Letter from Dr. Robert Temple, Director, Office of Drug Evaluation I, FDA, to Dr. Timothy R. Franson, Eli Lilly & Co., Sept. 30, 1996. Thereafter, the FDA approved Zyprexa for maintenance treatment of schizophrenia, FDA Nov. 9, 2000 Approval Letter; for the short-term treatment of acute manic episodes associated with bipolar I disorder as monotherapy, FDA March 17, 2000 Approval Letter; in combination with lithium or valproate, FDA July 10, 2003 Approval Letter; and for maintenance in the treatment of bipolar disorder. FDA Jan. 14, 2004 Approval Letter.

Multiple other second-generation antipsychotic drugs have been introduced since 1996. Atypical SGAs, in addition to clozapine (Clozaril), olanzapine (Zyprexa), and risperidone (Risperdal), now include quetiapine (Seroquel), aripiprazole (Abilify), and ziprasidone (Geodon). Pharmacotherapy, *supra* at 1224. Seroquel has been approved since 1997. Indicated for schizophrenia and acute manic or mixed episodes associated with bipolar disorder, Geodon entered the marketplace in March of 2001, and Abilify in November 2002. Abilify is also approved for treatment of depression. Transcript of Evidentiary Proceedings on Class Certification 827 ("Evid. Hr'g Tr."), March 28, 2008 through April 2, 2008.

C. Rapid Growth of Pharmaceuticals and SGAs

SGAs were and are marketed as providing more effective treatment with fewer side effects and better symptom reduction than the older—and far less expensive off-patent—FGAs. Expert Rep. of John Abramson, M.D., at 7, Feb. 28, 2007, Docket Entry No. 97 ("Abramson Rep."). Because of the severe and costly—in

both human and economic terms—nature of the illnesses that SGAs treat, insurance companies, believing the newer drugs to be more effective, have been willing to spend billions of dollars on them, despite the fact that they can cost up to 100 times more than the older antipsychotic medications. *Id.* (noting that, for example, Zyprexa costs more than twenty times the cost of Haldol, an FGA).

In 1994, when Risperdal, the second SGA after clozapine, was introduced, only five percent of schizophrenic patients were being prescribed an SGA; national spending on antipsychotic medications was $1.4 billion. *Id.* Ten years later, about ninety percent of schizophrenic patients nationally were being treated with SGAs rather than FGAs, and $10 billion was spent annually on antipsychotic medications. *Id.*; *see* Frank Decl. 4 (noting that in 2003, IMS Health estimated United States antipsychotic drugs sales to total $8.1 billion).

The dramatic rise in the costs of prescription drugs over the past decade is in large part due to SGAs, which now make up a substantial proportion of increased national spending on medication. In 2004, for instance, prescription drug expenditures in the United States were estimated at $188.5 billion, nearly five times the $40.3 billion the nation spent fourteen years earlier. Prescription Drug Trends, Kaiser Family Foundation (June 2006). "Sales of newer antipsychotics like Risperdal, Seroquel and Zyprexa totaled $13.1 billion in 2007, up from $4 billion in 2000." Tarkan, *supra* at F1; *see* Alex Berenson, *Lilly Adds Strong Warning Label to Zyprexa, a Schizophrenia Drug,* N.Y. Times, Oct. 6, 2007.

SGAs now account for about ninety percent of all antipsychotics drugs prescribed for all psychiatric purposes, regardless of whether they were approved for those indications or not. *See* Jeffrey A. Lieberman, *Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia,* 353 N. Eng. J. of Medicine 1209, 1210 (2005). Off-label prescriptions make up a substantial proportion of overall SGA sales.

Because many patients treated with antipsychotics are severely disabled, Medicare and Medicaid, as public health insurers, are the largest buyers of the drugs. Between 1994 and 2003, total Medicaid spending on all prescription drugs increased

by $25.9 billion, quadrupling from $8.4 billion to $34.3 billion; one-third of the increase, $8.5 billion, went towards increased expenditures on SGAs. Abramson Rep. 8. In 2003, three out of the top four drugs that Medicaid purchased were SGAs. *Id.* Zyprexa headed this list: Medicaid paid over $1.8 billion for olanzapine in each of 2003 and 2004, $500 million more than for any other single drug. *Id.*; *see* CMS Medicaid Drug Utilization data, ranked by Drug, 2003-2006. In 2005, the most recent year for which data is available, Medicaid paid over $1.6 billion for Zyprexa.

D. Lilly, with Zyprexa, Has Been Successful

Zyprexa has been a phenomenal success for Eli Lilly. Approved in more than 80 countries, it has been prescribed to more than 23 million people since 1996. Lisa Demer, *State Claims Drug Maker Hid Data,* Anchorage Daily News, Mar. 6, 2008. Over 73 million Zyprexa and Zyprexa Zydis prescriptions had been written by the end of 2006. *See* Rosenthal Decl., Ex. E.1 (citing IMS Health TRx Data).

From its launch, Zyprexa rapidly cut into Risperdal and Clozaril's market shares, even while the overall market for atypical antipsychotics grew substantially. Rosenthal Decl. 6. For both FDA-approved and off-label indications, Zyprexa has the largest market share for SGAs in the United States, *see* Lieberman, *supra* at 1210, and in 2003, was the seventh best-selling drug in the country with sales of $3.3 billion. Rosenthal Decl. 6. Although 2005 sales dropped to $2.5 billion, *id.*, Zyprexa sales now total $4.2 billion annually. Abramson Rep. 8. During plaintiffs' proposed class period, Zyprexa sales exceeded $22 billion. *See* Pfs.' Mem. in Opp. to Def.'s Mot. for Summary J., June 12, 2007 (filed under seal). In the United States, government payments for Zyprexa totaled $1.5 million in 2007. Alex Berenson, *In Trial, Alaska Says Lilly Concealed Risks of Schizophrenia Drug,* N.Y. Times, Mar. 6, 2008.

Zyprexa now accounts for approximately 27 percent of Lilly's total revenues, down from a high of 33 percent in 2002, *Fitch Affirms Eli Lilly & Co.'s IDR at 'AA'*, Business Wire, Sept.

> 26, 2007, but constitutes nearly fifty percent of the company's profits. Pretax profits from Zyprexa total $2 billion annually. J.K. Wall, *$2 Billion Challenge: Lilly Under Gun to Replace Aging Blockbuster Zyprexa*, Indianapolis Business J., Nov. 3, 2007. The average cost per prescription—roughly a month's supply—ranges from $250 to $350. *See* Summary J. Hr'g Tr. 74, June 22, 2007. At commonly prescribed doses, Zyprexa now costs about $8,000 per year. [Alex Berenson, *Lilly E-Mail Discussed Off-Label Drug Use,* N.Y. Times, Mar. 14, 2008]. Its costs, along with Lilly's profits, [are] expected to sharply decrease when its patent expires in 2011.

In re Zyprexa Prods. Liab. Litig., 253 F.R.D. 69, 98-102 (E.D.N.Y.).

B. Approved Uses of Zyprexa

Zyprexa was initially approved by the FDA for use in late 1996 for treatment of short-term manifestations of psychotic disorders. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 100; Decl. of Robert Cowan in Supp. of Pl.'s Mot. for Partial Summ. J. ("Cowan Decl."), Ex. 1 at 2 (Def.'s Objections and Responses to Pl.'s First Set of Reqs. for Admis.). By 2001, the drug was approved for maintenance treatment of schizophrenia and acute manic episodes associated with bipolar disorder. In March 2000, the FDA approved the addition of the subheading "schizophrenia" to the short term management of the manifestations of psychotic disorders. *See id.* at 2-3. During the same month, the FDA approved Zyprexa for the short-term treatment of acute manic episodes associated with bipolar I disorder. *See id.* at 3. In November 2000, the FDA approved new labeling for Zyprexa for the short-term treatment of schizophrenia in place of the management of the manifestations of psychotic disorders, and for maintaining treatment response in schizophrenic patients who had been stable for approximately eight weeks and were then followed for a period of up to eight months. *See id.* at 3. In 2004 Zyprexa was approved for

maintenance treatment of bipolar disorder. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 100.

The FDA has never approved Zyprexa for treatment of dementia or Alzheimer's dementia in the elderly. *See id.* at 4. Zyprexa's current label bears a "black box" warning that "Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death compared to placebo. . . . ZYPREXA (olanzapine) is not approved for the treatment of patients with dementia-related psychosis." Cowan Decl., Ex. 2 at 1 (2009 Zyprexa Label, as reproduced in 2009 Physicians' Desk Reference Electronic Library).

C. Off-Label Use of Zyprexa

Under the Food, Drug, and Cosmetic Act, a drug is misbranded when its labeling does not contain "adequate directions for use." 21 U.S.C. § 352(f)(l). The FDA cannot approve "adequate directions for use" until the drug is approved for a particular use or indication based on the FDA's finding that the drug is safe and effective, as established by accurate clinical trial data provided by the drug manufacturer. 21 U.S.C. §§ 352, 355(a), (d). A drug that is promoted for an unapproved ("off-label") indication or use does not contain "adequate directions for use" because the off-label indication or use is not included in the FDA approved labeling for the drug. Thus, the manufacturer's promoting a drug for an off-label use constitutes misbranding of the drug.

As the extensive deposition testimony of physicians in this litigation indicates, even though it is improper for a drug company to affirmatively merchandize a drug for an off-label use, doctors may voluntarily prescribe FDA-approved medicines for approved and unapproved uses as they believe appropriate in the exercise of their own professional judgment. *See* Aff. of

Andrew Rogoff in Supp. of Def.'s Mot. for Summ. J., Sept. 4, 2009 ("Rogoff Aff."), Ex. 20 at 18:1-11, 40:3-18 (Williams Depo. Tr., July 14, 2009); Rogoff Aff., Ex. 3 at 15:4-12 (Clark Depo. Tr., Apr. 15, 2009); *see also* Anna Wilde Mathews & Avery Johnson, *Boost for Off-Label Drug Use—FDA Would Let Firms Keep Doctors Informed on Unapproved Methods,* Wall St. J., Feb. 16, 2008, at A3 ("[O]ff-label uses of prescription drugs are a mainstay of the industry—an estimated 21% of drug use overall[.]"). Some off-label uses of a prescription drug may be medically necessary.

Numerous articles in medical journals and periodicals have reported off-label uses of atypical antipsychotics; some have endorsed such uses. *See* Def.'s Local Civil Rule 56.1 Statement of Undisputed Material Facts, Sept. 4, 2009 ("Def.'s SUF"), ¶ 122 & nn.178-80 (citing articles). In February 2004 a joint panel that included the American Diabetes Association, the American Psychiatric Association, the American Association of Clinical Endocrinologists, and the North American Association for the Study of Obesity, summarized common uses of atypical antipsychotics:

> [T]hey have become first-line agents for their indicated use and are increasingly being used off-label. In current practice, people who are likely to be treated with an [atypical antipsychotic] include those with schizophrenia spectrum disorders, bipolar disorder, dementia, psychotic depression, autism, and developmental disorders and, to a lesser extent, individuals with conditions such as delirium, aggressive behavior, personality disorders and posttraumatic stress disorder.

Rogoff. Aff., Ex. 106 at 596-97 (American Diabetes Association, et al., *Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes*, 27 Diabetes Care 596 (Feb. 2004)).

Depositions of Mississippi physicians, including physicians employed by Mississippi's Department of Mental Health, indicate that atypical antipsychotics are routinely prescribed off-label, and that Zyprexa is among the drugs that have frequently been prescribed for off-label uses for Medicaid and other patients. *See* Def.'s SUF ¶¶ 69-74, 121, 126-31 (citing physicians' deposition testimony).

D. Off-Label Promotion of Zyprexa

The State of Mississippi has offered substantial evidence of Lilly's efforts improperly to promote Zyprexa for off-label uses—that is, for the treatment of indications unrelated to schizophrenia or bipolar disorder, such as dementia, Alzheimer's-related dementia, depression, delirium, and other disorders. To support its claims, the State points to Lilly's guilty plea on federal misbranding charges as well as documentary evidence obtained through discovery. Lilly disputes the significance of much of this evidence.

1. Lilly's Federal Guilty Plea

On January 14, 2009, Lilly pled guilty to introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(l), and 352(f)(l). In its plea, Lilly admitted that the criminal charge arose "from Eli Lilly's illegal promotion of its drug Zyprexa in the United States between September 1999 and March 31, 2001." Cowan Decl., Ex. 3 ¶ 1 (Guilty Plea Agreement of Eli Lilly & Co., Jan. 14, 2009); *accord id.*, Ex. 1 at 3 (Def.'s Objections and Responses to Pl.'s First Set of Reqs. for Admis.) Lilly admitted:

> Between September 1999 and March 31, 2001, Eli Lilly promoted Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia. Zyprexa is not approved by the FDA for treatment of dementia or Alzheimer's dementia. Eli Lilly's promotion of Zyprexa for these additional intended uses

> violated 21 U.S.C. § 352(f)(1), because Zyprexa's labeling did not bear adequate directions for each of the drug's intended uses.

Cowan Decl., Ex. 3 ¶ 6 (a)(4).

2. Documentary Evidence of Off-Label Promotion

a) Promotion for Long-Term Care Patients

Lilly strategic planning documents from 1999-2000 suggest that Lilly targeted Zyprexa at elderly long-term care ("LTC") patients suffering from dementia. *See* Cowan Decl., Ex. 9 (Long-Term Care: Marketplace Management) at ZY203452450 (indicating that 47.7% of nursing home residents have dementia), ZY203452480-81 (showing Zyprexa held 45% of the LTC antipsychotic market); *id.* Ex. 10 (Zyprexa Business Plan Summary) at ZY205256791-92, -95 (outlining Lilly's "Strategic Planning Framework Summary" for the long-term care market). At the time, Lilly apparently hoped for a dementia label change in 2001. But Lilly never followed through with its attempt to obtain FDA approval for a dementia indication. Cowan Decl., Ex. 10 at ZY205256790, -95. Nevertheless, one of Lilly's identified "Critical [Commercial] Success Factors" was repositioning Zyprexa as "a mood stabilizer" and as "safe and effective in behavior (elderly)." *Id.* at ZY205256792.

A 2000 document entitled "LTC Strategy" indicated that nursing home treatment teams were among the "Key Players" in Lilly's efforts to promote Zyprexa for nursing home patients "[e]xhibiting behavioral symptoms (severe agitation and aggression) associated with dementia." Cowan Decl., Ex. 11. Lilly's nursing home "[o]bjective" was stated to be to "[c]apture new patients and switch / upgrade patients on other products to provide dependable control." *Id.* Another 2000 document entitled "LTC Messages" states that "Zyprexa offers dependable control" in patients with severe dementia. Cowan Decl., Ex. 12. A 2000 Zyprexa "U.S.

Business Summary" noted that from January to June of 2000 Zyprexa's "dementia antipsychotic" market share had climbed from 12% to 28%, but that Risperdal "continues to hold significant market share in [d]ementia." Cowan Decl., Ex. 14 at ZY203610668 (Aug. 16, 2000).

b) Promotion to Primary Care Physicians

An August 2000 "Zyprexa Primary Care Strategy and Implementation Overview" describes a campaign to increase Zyprexa use in the primary care physician ("PCP") market, which Lilly estimated to include more than 250,000 physicians—59,000 of whom were "key targets." *See* Cowan Decl., Ex. 15 at 1. The document states that, at the time, PCPs accounted for 18% of all retail antipsychotic prescriptions, of which Zyprexa's share was 18%. *Id.* "Nearly half of all PCP antipsychotic prescriptions [went] to patients age 65+." *Id.* The PCP campaign was to "launch" in October 2000. *Id.*

This document also notes that "Zyprexa's primary indications – schizophrenia and bipolar – are not viewed as PCP-treated conditions, so there's not a specific indication for Lilly reps to promote in the PCP segment." *Id.* The 2001 Zyprexa Primary Care *Q3 Implementation Guide,* which is marked "not for use in detailing," addresses the same issue:

> Until recently, antipsychotics didn't seem appropriate for primary care. But remember, the same could be said of antidepressants just 15 years ago. What changed? New drugs, like Prozac, were safer, better tolerated, and easy to use. In a similar way, ZYPREXA has a profile that is quite different from older antipsychotics and mood stabilizers. ZYPREXA is changing the way primary care physicians treat mental illness.

Cowan Decl., Ex. 17 at 10 (June 2001). The 2000 "Primary Care Strategy and Implementation Overview" proposes the following "Position":

> Zyprexa: The safe, proven solution in mood, thought, and behavioral disorders. We will emphasize safety to address barriers

> to adoption, and merchandise the brand's "Four years – Four million patients" base of experience. The word "solution" speaks to unmet medical need, and enables the PCP to take control of clinical situations that previously had led to referrals and/or poor outcomes. *"Mental disorders" is intentionally broad and vague, providing latitude to frame the discussion around symptoms and behaviors rather than specific indications.* We will position Zyprexa as the incremental next step in the PCP's expanding clinical orbit . . . .

Cowan Decl., Ex. 15 at 1 (emphasis in italics added).

An October 11, 2000 presentation entitled "Primary Care For Patients With Behavioral, Mood, and Thought Disturbances," addresses a number of sources of behavioral, mood, and cognitive issues:

> Behavioral, mood, and cognitive and thought disturbances are commonly seen by primary care physicians in patients with
> - Depression
> - Bipolar disorder (manic)
> - Thought disorders (psychoses)
> - Delirium
> - Dementia

Cowan Decl., Ex. 18 at ZY203912225 (Oct. 11, 2000). The presentation describes Zyprexa as a "broad spectrum antipsychotic," *id.* at ZY203912269, and offers evidence that "[o]lanzapine [Zyprexa] [r]educes [a]nxiety and [a]ggression" and improves "cognitive symptoms" in Alzheimer's disease, *id.* at ZY203912235, -61, and results in "[b]ehavioral [s]ymptom [r]eduction in [p]atients with [d]ementia," *id.* at ZY203912238. Atypical antipsychotics in general are claimed to be efficacious in treating anxiety or agitation, delirium, and dementia, as well as bipolar disorder and psychosis. *Id.* at ZY203912302.

The October 11, 2000 presentation also includes a case study of a hypothetical patient named Martha:

Case Study #2 Martha
• Older adult • Presenting symptoms o Aggressive o Agitated o Paranoid o Mildly delusional o Sleep disturbance • Physical exam, CBC, and neurological workup negative

Id. at ZY203912279. The presentation suggests that Martha would experience "[l]ess agitation, less confusion, less EPS/TD side effects with olanzapine." *Id.* at ZY203912290.

A meeting agenda dated October 25-27, 2000 indicates that a "Zyprexa PCP Launch Meeting" was held on those dates in Orlando, Florida. *See* Cowan Decl., Ex. 19 at ZY7300566. An October 2000 "Zyprexa Launch Meeting" presentation entitled "Viva Zyprexa" describes a strategy for promoting Zyprexa to PCPs. *See id.* at ZY7300425. The presentation states that "Zyprexa's success is crucial to corporate performance; PCPs represent the last major untapped segment." *Id.* It describes a "Vision" to "[e]xpand Zyprexa's market by redefining how primary care physicians treat mood, thought, and behavioral disturbances," *id.* at ZY7300428, and a "Strategic Intent" that "Zyprexa can and will become an everyday agent in primary care," *id.* at ZY7300429. A "focus on symptoms and behaviors found in mood, thought and behavioral disturbances" is urged. *Id.* at ZY7300431 (original emphasis).

An internal Lilly email of December 9, 2000 instructs sales representatives selling Zyprexa to PCPs to focus on patient symptoms of "behavior, thought, and mood disturbances,"

and notes that a "key benefit[]" of Zyprexa is its "efficacy in more than one area." Cowan Decl., Ex. 20 at 1 (email from Jill K. Lake to other Lilly employees, Dec. 9, 2000). The email suggests a response to physicians who say "I don't see those types of patients":

> The doctor is thinking that he does not see schizophrenic or bipolar patients, but he probably does see patients with symptoms of behavior, mood or thought disturbances. Need to focus on symptoms and patient types of Martha, David and Christine. Even if the doctor does not have diagnosis, he should treat anyway.

Id. at 2.

The 2001 Primary Care *Q3 Implementation Guide* similarly indicates that when a doctor says that he or she refers patients with schizophrenia or bipolar disorder to a psychiatrist, sales representatives should reply as follows:

> Doctor, that makes sense. Patients with moderate to severe symptoms of schizophrenia and bipolar disorder should be treated by a psychiatrist. However, in your own practice there are probably patients who may experience symptoms such as elevated mood, emotional withdrawal, and agitation who may benefit from ZYPREXA. Keep in mind that referrals can be expensive, time consuming, or logistically difficult.

Cowan Decl., Ex. 17 at 16.

A "Strategy Overview"· section of an undated "Zyprexa Implementation Guide," which is marked "not for use in detailing," similarly states:

> In order to succeed in the Primary Care market, we must focus on the *symptoms and behaviors* found in mood, thought, and behavioral disturbances. The sales aid has been organized in such a fashion that will allow you to identify specific symptoms for these disturbances. This message flow and the patient profiles (Martha, David, and Christine) will aid you in helping the physician to recognize these symptoms in patients he or she sees frequently. Use these tools to aim for early identification of

relevant patient types, as well as pointing out the important role that family members play.

Cowan Decl., Ex. 21 at 1 (original emphasis).

And a "story" for introducing the Martha profile to doctors is described in the 2001 Primary Care *Q3 Implementation Guide*:

> **Martha Spread**
>
> This is Martha. Martha is a widow who lives independently and has been your patient for some lime. She is becoming more complicated to manage, and you note increasing agitation. Her sleep is disturbed; she dozes during the day and is up most of the night. Her family has shared their concerns with you, saying, "She thinks we're trying to take advantage of her."
>
> Martha's family doesn't want to send her to a nursing home, but her agitation and confusion must be addressed. Your goals of treatment for Martha may include reducing her behavioral disturbances without impairing her cognitive functioning.
>
> **PROBE: Do you see patients like Martha? What medication(s) do you prescribe in treating her behavioral disturbances?**
>
> **ZYPREXA is a safe choice for Martha.** It has a low potential for drug interactions and anticholinergic side effects. Unlike drugs such as Haldol or Risperdal, ZYPREXA has an **EPS profile that is comparable to placebo** across the full dosing range.
>
> As I said before, ZYPREXA is quite different from older antipsychotics, so you can be confident treating Martha with a low dose. The most common side effect is somnolence, which is dose-dependent, so a starting dose of 5 mg—or even 2.5 mg—at bedtime is appropriate. In fact, this could help Martha's poor sleep.
>
> Doctor, ZYPREXA works. It has proven effective in reducing hostility as early as the first week. Early improvement will give Martha—and her family—confidence in the treatment you've prescribed. And ZYPREXA won't impair Martha's cognition; in

> fact, it actually improved cognition in prelaunch trials. (If the physician asks, a medical letter on the use of ZYPREXA in older populations is available.) Would you agree that these are important benefits for this patient?
>
> Doctor, will you give ZYPREXA a try in a patient like Martha? (Would you consider trying ZYPREXA in adults of all ages who present with secondary anger, agitation, and tension?)

Cowan Decl., Ex. 17 at 11 (original emphasis). The "Martha Spread" appears to highlight the symptoms that Zyprexa purportedly treats, rather than underlying diagnosis or indication.

At a December 2000 presentation it is indicated that in that month Lilly conducted a survey of district managers and sales representatives in an effort to "[i]dentify and understand areas of success and opportunities in the PCP market." Cowan Decl., Ex. 22 at 3 (Qualitative Telephone Focus Groups: Sales Rep and DM Topline Reaction to PCP Launch, December 2000). The survey pointed out that sales representatives had "the most success when their message centers on identifying patient types and treating symptoms instead of focusing on patient diagnosis." *Id.* at 4. "Martha" was noted as a "primary selling tool" with PCPs "because she [was] most easily recognizable." *Id.* at 7. The December 2000 presentation included a slide on "[w]hat's working in the message":

What's working in the message
• Creating a sense of urgency for PCPs o "You've tried other meds, but you haven't gotten the results you need." o "Your patient won't go to a psychiatrist. What are you going to do?" • Getting them to start in the office is the goal o "You are their last hope before the nursing home . . . " • Identifying patient types o Early adopters are prescribing for the elderly

- "Have you ever used low dose Haldol? That's your Zyprexa patient."

Id. at 9.

Sales representative call notes produced by Lilly support plaintiff's contention that, beginning in November 2000, Mississippi physicians were detailed about the Martha patient profile. *See, e.g.,* Cowan Decl., Ex. 27 at ZYMSAG2 1-20879 1917 (Lilly Call Note for Howard, Clark, M.D., Nov. 15, 2000) ("Zyprexa-pt type & reminded him to write it for pts like Martha."); *id.* at ZYMSAG2 1-20879 1922 (Lilly Call Note for Thomas Davis, M.D., Nov. 16, 2000) ("Zyprexa: somewhat familiar with it. Told me that study showed 5mg worked in Martha patient type, 10 would be as good effect. NV: cognition data."); *id.* at ZYMSAG2 1-20879 2024 (Lilly Call Note for Richard Carter, Jr., M.D., Jan. 11, 2001) ("Zyprexa message for patient Martha. He listened to messages and commented that he probably has pts like Martha. Describe Zyp pt again & benefits."); *id.* at ZYMSAG2 1-20879 2076 (Lilly Call Note for Bernard Harrell, M.D., Jan. 31, 2001) ("Probed to see which pts he was using Zyprexa in, then described pts like Martha. . . . Said he mainly uses Zyp for schizophrenia. . . . Zyp—keep trying to get him to write it for pts like Martha."); *id.* at ZYMSAG2 1-20879 2145 (Lilly Call Note for Hilton Fairchild, M.D., Mar. 1, 2001) ("Zyp—Martha message. Said Dr. Twente thinks Zyp is the greatest drug in the world & that everyone should be on it."); *id.* at ZYMSAG2 1-20879 2153 (Lilly Call Note for Miyako McCloud, Mar. 6, 2001) ("Zyp—she didn't have time for a full message but we discussed Martha as a patient type for Zyp.. [sic] Mentioned other pdts. She will sit down with me over lunch one day to further get into a Zyp message."); *id.* at ZYMSAG2 1-20879 2160 (Lilly Call Note for William Stephens, M.D., Mar. 8, 2001) ("Clinic appointment. . . . [W]ork on each physician to increase his knowledge of zyprexa and martha, david patient type." (original

ellipsis)); *id.* at ZYMSAG2 1-20879 2162 (Lilly Call Note for Tim South, M.D., Mar. 9, 2001) ("Breakfast at the clinic with Kim. She started a 'height tracker' with Robbie & tracking sheet with a few of the doctors.. [sic] Zyprexa—Martha & benefits of Zyprexa. Invited Drs Carter & Turner to golf program at the Dancing Rabbit. Dr. Carter will come to the program. They listened to messages but not much feedback as far as Zyp is concerned.").

E. Labeling and Warnings of Side-Effects to Patients and Medical Professionals

1. FDA Labeling and "Dear Doctor Letter"

The original 1996 Zyprexa package insert accompanying the drug disclosed information about possible side effects of administration of olanzapine based on clinical trials. The insert provided, in part, the following information:

> Adverse Events Occurring at an Incidence of 1% or More Among Olanzapine-Treated Patients in Short-Term, Placebo-Controlled Trials - - Table 1 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred during acute therapy (up to 6 weeks) of schizophrenia in 1% or more of patients treated with olanzapine (doses $\geq$ 2.5 mg/day) where the incidence in patients treated with olanzapine was greater than the incidence in placebo-treated patients.
>
> The prescriber should be aware that the figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence in the population studies.

Rogoff Aff., Ex. 112 at 11 (Zyprexa Package Insert, Oct. 2, 1996) (emphasis in original).

Two tables in the insert provided the results of placebo-controlled clinical studies of olanzapine-treated patients. The data indicates that, over a six-week administration of Zyprexa, six percent of olanzapine-treated patients reported weight gain, while only one percent of the placebo-treated patients reported weight gain. *Id.* at 12-16.

For several years, this information on the insert remained substantially the same insofar as it provided physicians information on reported weight-gain-related adverse events. During this period, the results of longer-term studies and clinical experience with Zyprexa and competing drugs supporting weight gain, hyperglycemia, and diabetes became widely known. *See* Parts E.2-4, *infra*.

In May 2000, the FDA undertook an analysis of the incidence of diabetes and hyperglycemia in patients using atypical antipsychotics. The director of the FDA's Division of Neuropharmalogical Drug Products requested additional safety information about Zyprexa from Lilly. In its letter, the FDA cited post-marketing reports of diabetes-related adverse events associated with Zyprexa use. In response, Lilly provided the FDA with clinical studies, data analysis, and case report reviews. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 119.

On September 11, 2003, the FDA announced it would require a warning about risks of hyperglycemia and diabetes mellitus and treating precautions to appear in the package insert of all atypical antipsychotics, including Zyprexa. Designed for prescribing doctors, the label noted that epidemiological studies and other information indicated that the relationship between the drug and hyperglycemia and diabetes was not yet fully understood. It reads as follows:

> **WARNINGS**
> **Hyperglycemia and Diabetes Mellitus**

> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hypersomolar coma or death has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics studied. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. . . .
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. . . .

Rogoff Aff., Ex. 116 at 1-2 (Letter from Russell Katz, M.D., Dep't of Health & Human Servs., to Gregory T. Brophy, Ph.D., Eli Lilly & Co., Sept. 11, 2003). The label did not mention weight gain or diabetes in the "warning to patients" section.

Lilly added the FDA-required language to the Zyprexa label on September 16, 2003. *See* Rogoff Aff., Ex. 117 at 6-7 (Zyprexa Package Insert, Sept. 16, 2003). At the FDA's request, on

March 1, 2004, it sent a "Dear Doctor" letter to physicians in the United States informing them of the 2003 label change. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 134-36.

2. Consensus Statement of American Diabetes Association and Other Learned Groups

In November 2003, the American Diabetes Association, American Psychiatric Association, American College of Clinical Endocrinologists, and the North American Association for the Study of Obesity convened a consensus development conference (the "ADA consensus conference") on the subject of the association between antipsychotic drugs and diabetes. An eight-member panel heard presentations from fourteen experts drawn from the fields of psychiatry, obesity, and diabetes, FDA representatives, and atypical antipsychotic drug manufacturers. The panel reviewed the relevant peer-reviewed English language scientific articles.

The ADA consensus conference concluded that Zyprexa and Clozaril posed an increased risk of diabetes as compared to other atypical antipsychotic drugs. The consensus statement produced by the conference declared that these relative risks as well as advantages of the drugs for individual patients in a heterogeneous population "should . . . influence drug choice." In part, its report concluded:

> There is considerable evidence, particularly in patients with schizophrenia, that treatment with [atypical antipsychotics] can cause a rapid increase in body weight in the first few months of therapy that may not reach a plateau even after 1 year of treatment. There is, however, considerable variability in weight gain among the various [atypical antipsychotics] . . . .
>
> ***

Clozapine [Clozaril] and olanzapine [Zyprexa] . . . produce the greatest weight gain.

***

Despite limitations in study design, the data consistently show an increased risk for diabetes in patients treated with clozapine [Clozaril] or olanzapine [Zyprexa] compared with patients not receiving treatment with [first generation antipsychotics] or with other [atypical antipsychotics]. The risk in patients taking risperidone and quetiapine is less clear; some studies show an increased risk for diabetes, while others do not. The two most recently approved [atypical antipsychotics], aripiprazole and ziprasidone, have relatively limited epidemiological data, but available clinical trial experience with these drugs has not shown an increased risk for diabetes.

***

[T]he risks of obesity, diabetes, and dyslipidemia have considerable clinical implications in this patient population and should . . . influence drug choice.

Even for those medications associated with an increased risk of metabolic side effects, the benefit to specific patients could outweigh the potential risks. For example, clozapine [Clozaril] has unique benefits for treatment-refractory patients and those at significant risk for suicidal behavior. Since treatment response in many psychiatric conditions is heterogeneous and unpredictable, physicians and patients can benefit from the availability of a broad array of different therapeutic agents.

***

These three adverse conditions [obesity, diabetes, and dyslipidemia] are closely linked, and their prevalence appears to differ depending on the [atypical antipsychotic] used. Clozapine [Clozaril] and olanzapine [Zyprexa] are associated with the greatest weight gain and highest occurrence of diabetes and

> dyslipidemia. Risperidone and quetiapine appear to have intermediate effects. Aripiprazole and ziprasidone are associated with little or no significant weight gain, diabetes, or dyslipidemia, although they have not been used as extensively as other agents.
>
> The choice of [atypical antipsychotic] for a specific patient depends on many factors. The likelihood of developing severe metabolic disease should also be an important consideration.

Rogoff Aff., Ex. 106 at 597-98, 600.

3. March 2007 FDA Letter

On March 27, 2007, the FDA raised new concerns about the adequacy of Zyprexa's warning label in a letter to Lilly:

> [W]e are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, and hyperlipidemia that is associated with olanzapine [Zyprexa] use . . . .
>
> Our overall goal is to improve labeling with regard to these findings so that clinicians will be better informed on what the risks are for their patients. They cannot make reasonable treatment decisions until they have such information. We do not feel that current labeling for . . . Zyprexa provides sufficient information on these risks, and we fully intend to insure that . . . labels are enhanced with the best available information to characterize these risks.

In re Zyprexa Prods. Liab. Litig., 253 F.R.D. at 141 (quoting Letter from Thomas Laughren, FDA, to Robin Pitts Wojcieszek, Eli Lilly & Co., Mar. 27, 2007).

4. Medical Community's Knowledge of Zyprexa's Risks

Numerous events represent moments at which a patient, health care provider, institution, or the medical community at large arguably discovered the dangers of Zyprexa in causing various deleterious metabolic effects. The evidence in related Zyprexa litigations, including medical records and the depositions of numerous doctors, suggests that it was widely known and

understood in the late 1990s among treating and prescribing physicians that weight gain might follow the administration of Zyprexa. The association between weight gain and heightened risk of diabetes was also broadly recognized by that time.

Formal events bringing this information to the medical profession include the September 2003 Zyprexa label change and contemporaneous press release, the 2003 consensus statement of the American Diabetes Association, and the March 2004 "Dear Doctor" letter distributed nationwide to physicians by Lilly. *See* Parts E.1-3, *supra.*

In its June 2007 memorandum, order, and judgment on four motions for summary judgment in individual Zyprexa injury cases, this court found that, for purposes of those motions, the March 2004 "Dear Doctor" letter would be considered the latest possible date on which members of the medical community knew or should have known about Zyprexa's obesity- and diabetes-related risks to patient health. *See, e.g., Souther*, 489 F. Supp. 2d at 278. In *Souther*, applying the relevant "learned intermediary" doctrine, it was determined that Souther's claim was barred by the statute of limitations:

> Diabetes developed and Zyprexa was prescribed [to plaintiff Cusella] years before the September 2003 label change. *At least from the date of March 2004 Dear Doctor letter, the causal connection between Zyprexa and diabetes was known to Dr. Ganime, Cusella's treating physician.* Since Lilly's duty to warn ran to Dr. Gamine rather than Cusella, it became Dr. Ganime's duty from that point onwards to disclose to Cusella that Zyprexa might exacerbate his diabetes, and that it may have been the impetus behind Cusella's insulin-dependancy in the first place.
>
> Dr. Ganime's medical records and deposition testimony . . . show that Cusella was warned numerous times about the link between Zyprexa and diabetes. While the pre-label change warnings Dr. Ganime received from Lilly *may* not have been adequate to absolve Lilly of liability to Cusella, those warnings

> Cusella received from Dr. Ganime following the label change placed him on notice that use of Zyprexa might have worsened his diabetes and caused him to become insulin-dependent.
>
> *Measured either against the date Cusella developed diabetes—August 1999—or the latest possible date Dr. Gamine was aware of the potential causal connection between Zyprexa and diabetes—March 2004*—Pennsylvania's two year statute of limitations had run on Cusella's claim before he filed this suit in April of 2006.

Id. (emphases added; citations to record omitted).

The March 1, 2004 date represents the "latest possible date" prescribing physicians and, in effect, their patients were deemed to be aware of the potential causal connection between Zyprexa and a range of metabolic conditions. Nevertheless, it was held in *Souther* and related cases that a fact-specific analysis is necessary to determine when an individual patient—whether independently or by operation of the learned intermediary doctrine—knew the potential causal connection between Zyprexa and adverse health effects. The facts in many individual cases indicate a much earlier date of discovery. *See, e.g.,* Appendices A-D of *Souther*, No. 06-CV-1729, Docket Entries Nos. 88-1 to 88-4 (June 11, 2007) (including relevant depositions demonstrating doctors' awareness of Zyprexa's association with patient weight gain).

F. Mississippi Zyprexa Use and Medicaid Benefits

Zyprexa has been prescribed hundreds of thousands of times in Mississippi, to tens of thousands of individual patients. Dr. Meredith Rosenthal, one of the State's experts, prepared estimates of the number of Mississippi Zyprexa prescriptions, the number of unique patients, and the total volume of sales. She estimates that Zyprexa has been prescribed nearly one million times in Mississippi. Rogoff Aff., Ex. 34 ¶ 23 (Estimation of Loss-of-Value Damages and Alternative Measures for the Calculation of Civil Penalties Related to the Unlawful Marketing of

Zyprexa, Decl. of Meredith Rosenthal for the State of Mississippi). A substantial proportion of Mississippi Zyprexa prescriptions have been paid for through Mississippi's Medicaid program. Dr. Rosenthal estimates that Medicaid-reimbursed sales of Zyprexa constitute over half of all Mississippi Zyprexa sales, totaling over $155 million. *Id.*

Under the federal Medicaid statute, states are permitted, but not required, to offer a pharmacy benefit to Medicaid-eligible citizens. *See* 42 U.S.C. §§ 1396a(a)(10), 1396d(a)(12). Mississippi has chosen to offer prescription drug benefits through its Medicaid program. *See* Rogoff Aff., Ex. 1 § 2.01 (Mississippi Division of Medicaid Provider Policy Manual, Jan. 1, 2006). The parties disagree about the scope of the State's obligation to reimburse prescriptions under its Medicaid prescription drug benefit. The State asserts that it is required to reimburse only for "medically necessary uses." Pl.'s Response & Incorporated Memo. of Law in Opp'n to Def.'s Mot. for Summ. J., Oct. 20, 2009 ("Pl.'s Response"), at 4 (citing 42 U.S.C. §§ 1396-1, 1320c-5(a)).

The State Division of Medicaid Provider Policy Manual defines "medically necessary" as follows:

> "Medically necessary" or "medical necessity" shall mean health care services that a provider, exercising prudent clinical judgment, would provide to a patient for purposes of evaluating, diagnosing, or treating an illness, injury, disease or its symptoms, and that are:
>
> - appropriate and consistent with the diagnosis of the treating provider and the omission of which could adversely affect the patient's medical condition; **and**
> - compatible with the standards of acceptable medical practice in the United States; **and**
> - provided in a safe, appropriate and cost-effective setting given the nature of the diagnosis and the severity of the symptoms; **and**

- not provided solely for the convenience of the beneficiary or family, or the convenience of any health care provider; **and**
- not primarily custodial care; **and**
- there is no other effective and more conservative or substantially less costly treatment service and setting available; **and**
- the service is not experimental, investigational or cosmetic in nature.

Rogoff Aff., Ex. 1 § 53.22.

Lilly disputes the State's construction of its statutory obligations, arguing that the State is required to reimburse prescriptions of covered outpatient drugs for all "medically accepted indications." Memo. of Law in Supp. of Def.'s Mot. for Summ. J., Sept. 4, 2009 ("Def.'s Memo."), at 3-4 (quoting 42 U.S.C. §§ 1396r-8(a)(1), (d)(1)(b) & (k)(6)). Such medically accepted indications include, Lilly contends, "FDA-approved uses *and* any off-label uses supported by three compendia." *Id.* at 4 (emphasis in original); Def. SUF ¶ 55. One of the compendia in question supports use of Zyprexa to treat a wide variety of off-label indications, including: Alzheimer's-induced psychotic disorder, dementia-related anxiety, delirium, bipolar depression, and treatment-resistant depression. Rogoff Aff., Ex. 43 §§ 4.5C, 4.5E, 4.5L, 4.5N, 4.5O. Mississippi has not contested Lilly's position that many relevant off-label uses of Zyprexa are supported by the compendia. *See* Def.'s Memo. at 41; Pl.'s Response to Def.'s Statement of Undisputed Facts, Oct. 20, 2009, ¶ 59. It would appear that few, if any, of the prescriptions the State challenges would be excluded from Medicaid reimbursement were Lilly's view adopted by the court or a jury.

G. Aggregate Evidence Offered by Mississippi

1. Evidence of Overpricing of Zyprexa

Mississippi's expert Dr. Rosenthal has opined that "the unlawful conduct alleged by the State of Mississippi regarding the marketing and lack of disclosure of complete information about product risks and efficacy of Zyprexa by Lilly resulted in economic harm to public payers and consumers." Rogoff Aff., Ex. 34 at 1. Dr. Rosenthal uses a "loss-of-value" statistical analysis to derive an estimate of damages using data from Mississippi's Medicaid program. *See id.* Dr. Rosenthal offered a similar conclusion based on the same type of analysis in the Zyprexa Third-Party Payors litigation. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 156-62; *see also* Part IV.E.2, *infra*. Dr. Rosenthal's expert report in this case explicitly incorporates and relies on the reports she submitted in that litigation. Rogoff Aff., Ex. 34 ¶ 2.

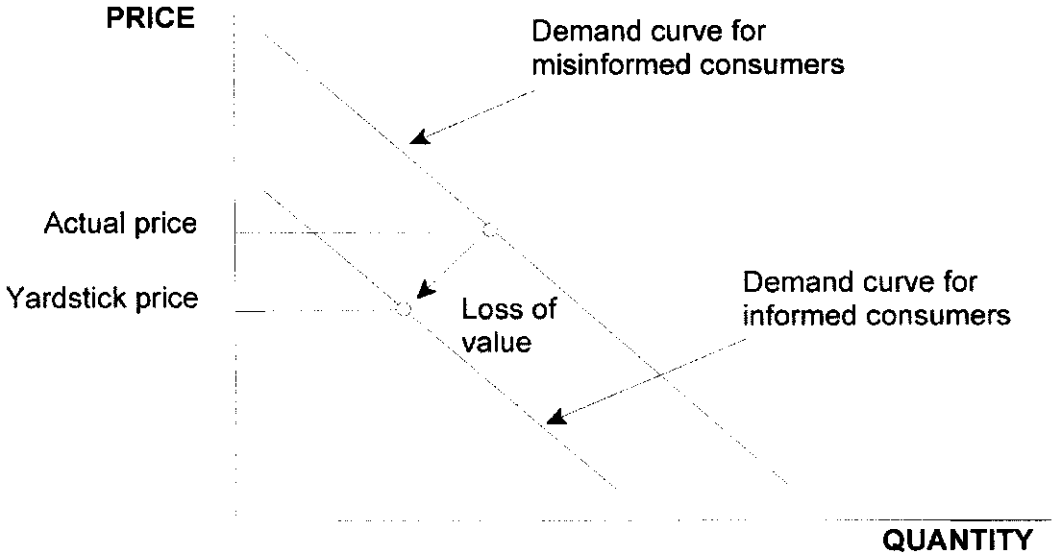
The court previously described Dr. Rosenthal's loss-of-value methodology as follows:

> Dr. Rosenthal . . . provided an opinion on the value of Zyprexa and attempted to quantify the monetary difference between what was represented and paid for and what the class received. She began with the basic premise of health economics that people are willing to pay higher prices for high-quality health care than for lower-quality health care. She notes that Dr. Kolassa, one of Lilly's own experts, describes pharmaceutical pricing just that way:
>
> > "The primary principle that should guide every pricing decision is that the price should reflect the value of the product to the customer."
> >
> > "When a product delivers better outcomes, it deserves to be priced at a premium relative to competitors. Should the outcomes not differ from competitive products, a parity price is in order. Worse relative outcomes should be reflected by a price that is lower than prevailing levels."

Although the pharmaceutical market is unique in many ways, "this basic premise has been shown to hold true in pharmaceutical pricing as well."

Her "loss of value" methodology attempts to demonstrate that the expected value of Zyprexa to patients was inflated by Lilly's allegedly fraudulent behavior. (A "loss of value" damage model is different from a "but-for" calculation of the effect of Lilly's alleged fraud on Zyprexa's prices.) The following chart demonstrates the relationship between loss of value and misinformation:

Demand Curve Change From Lilly Unlawful Conduct



Pls.' Reply Mem. 53.

To determine estimated damages, Dr. Rosenthal employed standard "yardstick" techniques used by healthcare economists. She selected two of Zyprexa's comparators, Seroquel, a branded SGA [second-generation antipsychotic] launched in 1997, and perphenazine, a generic FGA [first-generation antipsychotic], as yardsticks against which she measured Zyprexa's value. They were chosen after she considered, and rejected as less valid, other possible sources of willingness-to-pay estimates. According to the

> . . . scores from [a] cost-effectiveness study comparing the value of second-generation atypical antipsychotics and the first-generation typical antipsychotic perphenazine, the two medications are of "equal economic value" to Zyprexa.
>
> Dr. Rosenthal does not claim that Zyprexa's actual price would have been the same as the other medications had Lilly provided different information about side effects and effectiveness. Instead, she uses price as a proxy for the loss of value, or disappointment of consumer expectations, that occurred as a result of Lilly's alleged fraud. Her analysis may assist the jury in analyzing the overpricing claim.
>
> The value of a product to patients relates to a manufacturer's strategic pricing decisions. A text on pharmaceutical pricing written by Lilly's own expert recognizes that drug launch prices reflect the value that customers can expect from the drug (as offset by possible adverse effects) compared to what is charged for competitive drugs. Lilly itself recognizes the interrelationship between pricing and comparative expected value to the consumer.

253 F.R.D. at 159-61 (citations and internal cross-references omitted).

Dr. Rosenthal was directed by Mississippi's counsel to "extend [her] earlier analysis of the impact of Lilly's allegedly unlawful marketing of Zyprexa on a national class of endpayers to public programs in Mississippi." Rogoff Aff., Ex. 34 at 1. She concluded that "[t]he circumstances surrounding the sales and marketing of Zyprexa in Mississippi are essentially the same as those affecting the nationwide [c]lass." *Id.* Her analysis accordingly proceeded in a similar fashion:

> [The loss-of-value] approach is intended to capture the difference between what payers understood Zyprexa to be worth and the value they would have attached to it with full information. To operationalize this notion, I developed yardsticks based on the clinical literature that represent the true economic value of Zyprexa. Based on comparative effectiveness data from a definitive national randomized control trial, I have chosen the prices of Seroquel and perphenazine as alternative yardsticks for this measure of economic value. In addition, I estimated the number of prescriptions that were caused by Lilly's allegedly

illegal promotion of Zyprexa for unapproved uses ("off-label promotion"). In the case of these uses, for which I have been instructed by counsel to assume there is ambiguous or negative evidence of Zyprexa's utility, I count the entire expenditure to be lost value (i.e., I apply a yardstick of zero dollars).

***

As I did in my original analysis, I generate alternative damages estimates for scenarios in which the alleged level of off-label promotion varies. In particular, I model two cases which reflect different assumptions about missing data. In the "lower bound" scenario I assume that the time-limited data I have that document effort spent on off-label promotion represent the only off-label promotion that occurred. In the "upper bound" scenario I assume that during the period of time for which I am missing data, the level of off-label promotion is the same as the period where I do have data. These assumptions, in turn, affect the damages estimates because I have been instructed by counsel to assume that the value of those units induced by off-label promotion is zero, rather than the value associated with one of the yardsticks.

. . . The range of loss-of-value estimates is $14.9 million using the Seroquel yardstick and the lower-bound quantity yardstick and $122.2 million using the perphenazine yardstick and the upper-bound quantity yardstick. Table 1 shows a summary of total loss-of-value damages for the two yardsticks and alternative assumptions about the level of alleged off-label promotion.

Table 1
Summary of "Loss-of-Value" Damages ($)

Yardstick	*Lower Bound*	*Upper Bound*
Seroquel	$14,947,292	$40,898,495
Perphenazine	$71,990,519	$122,179,329

Id. ¶¶ 8, 11-12.

2. Evidence of Costs Due to Zyprexa-Induced Diabetes

Mississippi offers Dr. Rosenthal's expert opinion regarding "the magnitude of the costs of illness caused by Zyprexa." *Id.* ¶ 25. Dr. Rosenthal calculates "the impact of . . . medical

costs associated with diabetes" resulting from Zyprexa use. *Id.* ¶ 26. While diabetes is only one of several adverse consequences associated with Zyprexa, "diabetes is likely to be among the most important conditions caused by Zyprexa and its medical care is likely to be the largest source of economic costs." *Id.*

To arrive at her calculation, Dr. Rosenthal multiplied three factors: (1) "the attributable risk of diabetes for Zyprexa," based on an estimate of the rate of diabetes cases attributable to Zyprexa from a published epidemiological study; (2) the number of patients who took Zyprexa, based on Dr. Rosenthal's own estimate of the number of unique Mississippi Zyprexa users; and (3) "the incremental cost of medical care caused by diabetes," based on an estimate by the American Diabetes Association. *Id.* ¶ 32. This formula resulted in an estimated $2,736,798 per year in diabetes-related costs in Mississippi.

Dr. Rosenthal noted that not all of these estimated diabetes-related costs would have been borne by the State of Mississippi, and that "[t]he data used for this calculation may not account for all the dynamics of treatment changes and disease progression that could affect outcomes for individual patients." *Id.* ¶ 33.

3. Evidence that Zyprexa Was Over-Prescribed

Mississippi's expert Dr. John David Abramson offers his opinion that Lilly's alleged improper promotional conduct would have "had a substantial effect on the prescribing behavior of doctors and the willingness of the health care market to pay for Zyprexa," and that "Lilly's exploitation of various sources from which doctors derive prescription drug information . . . would have served to increase the quantity of prescriptions written for Zyprexa." Rogoff Aff., Ex. 36 at 1 (Expert Rep. of John Abramson, M.D., Feb. 28, 2007, updated Nov. 20, 2008). Dr. Abramson notes in particular that "Lilly used an unsubstantiated economic claim to justify its

off-label promotion," namely that managed care organizations "would save money by allowing [primary care physicians] to prescribe Zyprexa off-label." *Id.* ¶ 191. Relied on in addition is a demonstration of the methodological flaws of two studies that Lilly used to show that Zyprexa was more cost-effective than first-generation antipsychotics. *Id.* ¶ 192. Dr. Abramson served as an expert for the Third-Party Payors, and offered similar opinions and analyses. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 174-76.

Dr. Rosenthal also provided an estimate of "the number of prescriptions that were caused by Lilly's allegedly illegal promotion of Zyprexa for unapproved uses." Rogoff Aff., Ex. 34 ¶ 8.

IV. Law

A. Summary Judgment

Summary judgment is appropriate only if "there is no genuine issue as to any material fact and if the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *see also Mitchell v. Washingtonville Central Sch. Dist.*, 190 F.3d 1, 5 (2d Cir. 1999). Summary judgment is warranted when, after construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor, there is no genuine issue as to any material fact. Fed. R. Civ. P. 56(c); *see Anderson*, 477 U.S. at 247-50, 255; *Sledge v. Kooi*, 564 F.3d 105, 108 (2d Cir. 2009).

The burden rests on the moving party to demonstrate the absence of a genuine issue of material fact. *Goenaga v. March of Dimes Birth Defects Found.*, 51 F.3d 14, 18 (2d Cir. 1995); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). If the moving party appears to meet this burden, the opposing party must produce evidence that raises a material question of fact to defeat the motion. *See* Fed. R. Civ. P. 56(e). This evidence may not consist of "mere

conclusory allegations, speculation or conjecture[.]" *Cifarelli v. Village of Babylon*, 93 F.3d 47, 51 (2d Cir. 1996); *see also Delaware & Hudson Ry. v. Consolidated Rail Corp.*, 902 F.2d 174, 178 (2d Cir. 1990) ("Conclusory allegations will not suffice to create a genuine issue.").

B. Choice of Law

In a multidistrict litigation like the present one, "a transferee court applies the substantive state law . . . of the jurisdiction in which the action was filed"; in this case Mississippi. *Menowitz v. Brown*, 991 F.2d 36, 40 (2d Cir. 1993) (citing *Van Dusen v. Barrack,* 376 U.S. 612 (1964)); *see also In re Temporomandibular Joint Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996). Nevertheless, "a transferee federal court should apply its interpretations of federal law, not the constructions of federal law of the transferor circuit." *Menowitz*, 991 F.2d at 40 (citing *Coker v. Pan Am. World Airways, Inc. (In re Pan Am. Corp.),* 950 F.2d 839, 847 (2d Cir.1991)); *see also Temporomandibular*, 97 F.3d at 1055; Daniel A. Richards, *An Analysis of the Judicial Panel on Multidistrict Litigation's Selection of Transferee District and Judge*, 78 Fordham L. Rev. 311, 316 (2009) ("On issues of state law, an MDL transferee court will apply to each constituent action . . . the state law that the transferor court would have applied had the [Judicial Panel on Multidistrict Litigation] decided against transfer. On issues of federal law, however, the transferee court is bound by the law of the federal circuit in which the transferee court sits.").

Orders of a transferee court are appealed to the court of appeals where the transferee court sits, in this case the Second Circuit Court of Appeals. *Hill v. Henderson*, 195 F.3d 671, 677 (D.C. Cir. 1999); *In re Food Lion, Inc.*, 73 F.3d 528, 532-33 (4th Cir. 1996); *FMC Corp. v.*

Glouster Engineering Co., 830 F.2d 770, 771-72 (7th Cir. 1987). Mississippi's law controls, subject to due process and applicable federal statutes and rulings.

C. Mississippi's State-Law Claims

1. Medicaid Fraud Control Act (MFCA)

The Mississippi Medicaid Fraud Control Act (MFCA) provides for civil liability where a person makes or causes to be made a "false, fictitious or fraudulent" claim for Medicaid benefits, Miss. Code Ann. § 43-13-213, or a false statement in an application for Medicaid benefits or for use in determining rights to a Medicaid benefit, *id.* § 43-13-205(1) & (2). Civil liability also attaches where a person conspires to defraud the Medicaid program "by obtaining or aiding another to obtain the payment or allowance of a false, fictitious or fraudulent claim for medicaid benefits." *Id.* § 43-13-211.

The MFCA provides for "a civil penalty equal to the full amount received, plus an additional civil penalty equal to triple the full amount received." *Id.* § 43-13-225(1).

2. Product Liability Act (PLA)

The Mississippi Product Liability Act (PLA) permits an action for damages where a "product was defective because it failed to contain adequate warnings or instructions," or where it "breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product." Miss. Code Ann. § 11-1-63(a)(i)(2) & (4). Liability under these sections is limited to circumstances in which "the manufacturer or seller knew or . . . should have known about the danger that caused the damage for which recovery is sought and that the ordinary user or consumer would not realize its dangerous condition." *Id.* § 11-1-63(c)(i).

The CPA's definition of "adequate product warning or instruction" incorporates the "learned intermediary doctrine"—that is, the rule that the manufacturer's duty to warn runs to the prescribing physician rather than the patient:

> An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or *in the case of a prescription drug . . . taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug . . . .*

Id. § 11-1-63(c)(ii) (emphases added); *see also Janssen Pharmaceutica, Inc. v. Bailey*, 878 So.2d 31, 57 (Miss. 2004) ("[W]here prescription drugs are concerned, a manufacturer's duty to warn only extends to physicians and not to laymen."); Part IV.D, *infra.*

To establish a claim under the PLA, a plaintiff must prove that "the defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought." Miss. Code Ann. § 11-1-63(a)(ii).

The PLA provides liability for damages caused by defective products, "except for commercial damages to the product itself." *Id.* § 11-1-63. Although the PLA does not define "commercial damages to the product itself," Mississippi courts have adopted the economic loss doctrine, under which recovery is not available for purely economic damages, as opposed to physical injury to persons or property. *See State Farm Auto. Ins. Co. v. Ford Motor Co.*, 736 So. 2d 384, 388 (Miss. Ct. App. 1999); *Miss. Chem. Corp. v. Dresser-Rand Co.*, 287 F.3d 359, 364 n.3 (5th Cir. 2002).

3. Consumer Protection Act (CPA)

The Mississippi Consumer Protection Act (CPA) prohibits "[re]presenting that goods or services have . . . approval, characteristics, ingredients, uses, [or] benefits . . . that they do not have," and "[r]epresenting that goods or services are of a particular standard, quality, or grade . . . if they are of another." Miss. Code Ann. § 75-24-5(2)(e) & (g).

Anyone "who purchases . . . goods . . . primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property, real or personal, as a result of . . . a method, act or practice prohibited by Section 75-24-5 may bring an action at law . . . to recover such loss of money or damages for the loss of such property." *Id.* § 75-24-15. The CPA also provides for "a civil penalty in a sum not to exceed Ten Thousand Dollars ($10,000.00)" for each knowing and willful violation of the Act. *Id.* § 75-24-19(1)(b).

Assuming that a "knowing and willful violation of the Act" is found by the finder of fact, the appropriate penalty, up to $10,000, is entirely in the discretion of the court. *See* Oct. 21, 2009 Hr'g Tr. at 15:24-16:5 (statement of Mississippi's counsel). Mississippi argues that its claim for statutory penalties under the CPA is the only one of its claims that does not "demand proof of reliance or causation to survive." Pl.'s Response. at 29. Rather, statutory penalties are said to be "triggered merely by Lilly's representations" as to Zyprexa's characteristics and benefits. *Id.*

4. Common-Law Claims

Causation is an essential element of the State's fraud, negligence, and unjust enrichment claims under Mississippi common law. *See Owens Corning v. R.J. Reynolds Tobacco Co.*, 868 So.2d 331, 343 (Miss. 2004) ("Proximate causation must be proved to establish a fraud claim."); *id.* at 342 (holding that plaintiff asbestos manufacturer that had paid compensation for injuries

caused by asbestos and that sought recovery in unjust enrichment from tobacco producers whose products allegedly contributed to those injuries, "would have to prove that Tobacco Defendants were liable for injuries suffered by the asbestos claimants, for which the claimants have been compensated by" the asbestos manufacturer); *Busick v. St. John*, 856 So.2d 304, 307 (Miss. 2003) ("An essential part of the claim in a personal injury tort case is to demonstrate, not only the extent of the injury, but that the negligence of the defendant was the proximate cause of the injury.").

Mississippi concedes that its common-law claims "demand proof of reliance or causation in order to survive." Pl.'s Response at 29.

5. Statute of Limitations

Mississippi's claims are not time-barred. As a matter of Mississippi law, "[s]tatutes of limitations in civil cases shall not run against the state, or any subdivision or municipal corporation thereof." Miss. Code Ann. § 15-1-51. Whether equitable bars or due process limitations affect the life of a State claim need not now be decided. *Cf. Miss. State Highway Comm'n v. New Albany Gas Systems,* 534 So.2d 204, 208 (Miss.1988) ("The weight of authority is to the effect that, generally speaking, laches will not be attributed to the State, especially when it is acting in its sovereign capacity or exercising rights on behalf of the general public . . . .").

D. Learned Intermediary Doctrine

"When the product in question is a prescription drug, Mississippi follows the learned intermediary doctrine." *Janssen Pharmaceutica*, 878 So.2d at 58 (quoting *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir.1992)); *see also Moore ex rel. Moore v. Memorial Hosp. of Gulfport*, 825 So.2d 658, 662 (Miss. 2002) ("[T]he learned intermediary doctrine has been adopted by this Court[.]"). Under the learned intermediary doctrine, "[p]laintiffs bear the

burden of establishing that [a prescription medication] was the cause of their injuries and that an adequate warning would have convinced the treating physician not to prescribe the product." *Janssen Pharmaceutica*, 878 So. 2d at 58 (internal quotation marks omitted). Mississippi has also codified the learned intermediary doctrine in its Product Liability Act. *See* Part IV.C.2, *supra*; Miss. Code. Ann. § 11-1-63(c)(ii); *see also Janssen Pharmaceutical*, 878 So.2d at 57.

The learned intermediary defense is an

> aspect of proportionality that shifts at least some of the burden of protecting patients from pharmaceutical manufacturers to treating physicians . . . . [T]he learned intermediary rule cannot be viewed as an all-or-nothing regulation that absolves the manufacturer, shifting the onus entirely to the treating physician, but its force in ameliorating liability for damages of the manufacturers cannot be ignored.

Souther, 489 F. Supp. 2d at 244. There is a strong trend in prescription drug failure-to-warn cases to reiterate and apply this well established doctrine. *See, e.g., Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (holding that a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician (citing *Plummer v. Lederle Laboratories, Div. of American Cyanamid Co.*, 819 F.2d 349, 358-59 (2d Cir. 1987)); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 780 (S.D. Tex. 2008) (granting summary judgment for defendant upon finding that prescribing physician was aware of Zyprexa's suicide-related risks that an adequate warning would have provided and that plaintiff had presented no evidence physician would not have prescribed Zyprexa had defendant provided him with an alternate warning label), *aff'd*, 321 F. App'x 350 (5th Cir. 2009); *Allgood v. GlaxoSmithKline PLC*, No. 06-3506, 2008 WL 483574, at *4 (E.D. La. Feb. 20, 2008) (granting summary judgment for defendant because prescribing doctor's "testimony

clearly reveal[ed] that stronger warnings concerning the risk of suicide would not have changed his decision to prescribe"), *aff'd sub nom. Allgood v. SmithKline Beecham Corp.*, 341 F. App'x 701 (5th Cir. 2009). It need not be decided now whether a responsible party or institution equivalent to a learned intermediary breaks the causal connection between users' harms and producers' negligence. *See* Part VI.A, *infra*.

E. Individual Issues and Aggregate Proof in Class Actions, Quasi-Class Actions, and Structural Class Actions

Crucial to Mississippi's claims is statistical evidence relating to the population of patients who received Zyprexa in Mississippi. The appropriate uses of such evidence have been addressed in numerous decisions in class action cases, including the court's class certification decision in the Zyprexa Third-Party Payors litigation. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69 (E.D.N.Y. 2008); *see also, e.g., McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008).

The present case is not a Rule 23 class action or a quasi-class action. *See* Fed. R. Civ. P. 23; *see also, e.g., In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 262 (E.D.N.Y. 2006) ("The court, magistrate judge and special masters will continue to administer this litigation as a quasi-class action."). Mississippi brings suit individually. In this respect, decisions in class actions concerning the use of statistical or aggregate evidence are not directly on point.

Conceptually and structurally, however, the State's suit is predicated on numerous acts of fraud and other delicts alleged to have affected a statewide population of prescribing physicians and patients. In effect, Mississippi's individual claim is structured on the foundation of many thousands of conceptually separate claims, coordinated and aggregated by the State for purposes of recovering a portion of its overall Zyprexa-related costs through its Medicaid reimbursement

program. The court will refer to an individual claim structured in this way as a *"structural" class action.*

The Zyprexa MDL thus includes three types of aggregate litigation: (1) *a Rule 23 class action, see* Part IV.E.2, *infra*; *In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69 (E.D.N.Y. 2008); (2) thousands of individual claims treated as a *quasi-class action, see* Part II.B, *supra*; *In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 262 (E.D.N.Y. 2006); and (3) *structural class actions*, where an individual plaintiff—here, the State of Mississippi—brings claims for reimbursements it provided, structured on and founded upon large numbers of individual patients' medical costs for Zyprexa prescriptions and treatment of subsequent conditions. These are all examples of the aggregation of claims studied and partially covered in the American Law Institute's recent report on aggregate litigation. American Law Institute, Principles of the Law of Aggregate Litigation, (Proposed Final Draft, Apr. 1, 2009).

Mississippi's suit is in the nature of a structural class action. The extensive case law regarding the uses and limitations of aggregate evidence in Rule 23 class actions is applicable.

1. Individualized Proof Rule

Despite this court's view to the contrary, appellate class action decisions have held that issues of reliance, loss-causation, and injury are inappropriate for aggregation, due to the need to prove these elements on an individualized basis for each victim or injured party. *See, e.g., McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 223-30 (2d Cir. 2008); *Fotta v. Trustees of United Mine Workers of Am.*, 319 F.3d 612, 619 (3d Cir. 2003); *Doe v. Chao*, 306 F.3d 170, 183-84 (4th Cir. 2002); *McManus v. Fleetwood Enters., Inc.*, 320 F.3d 545, 549 (5th Cir. 2003); *Oshana v. Coca-Cola Co.*, 472 F.3d 506, 513-514 (7th Cir. 2006); *St. Jude Med., Inc.*, 522 F.3d 836, 838-39 (8th Cir. 2008); *Poulos v. Caesars World, Inc.*, 379 F.3d 654, 658, 666 (9th Cir.

2004); *Heffner v. Blue Cross & Blue Shield of Ala., Inc.*, 443 F.3d 1330, 1344 (11th Cir. 2006); *see also, e.g., In re Neurontin Marketing, Sales Practices, & Liab. Litig.*, 257 F.R.D. 315, 322-27 (D. Mass. 2009).

Recent attempts to overcome the individualized proof requirement through expert analyses using advanced statistical methods have been rejected by some intermediate courts of appeal, notably by the Court of Appeals for the Second Circuit in *McLaughlin v. Am. Tobacco Co.*, *supra*, and in several subsequent decisions relying on *McLaughlin*. *See, e.g., In re Neurontin Marketing, Sales Practices, & Liab. Litig.*, 257 F.R.D. at 322-27; *Gutierrez v. Wells Fargo & Co.*, No. C 07-05923, 2009 WL 1247040, at *4-5 (N.D. Cal. May 5, 2009).

Together, this large body of case law constitutes a now widely held view of aggregate litigation, particularly in the products liability or fraud context, that statistical proof is in most instances insufficient to show reliance, loss-causation, or injury on the part of individual class members or claimants (the "Individualized Proof Rule"). As indicated below this view is far from universal. It has, for example, been rejected by this court in the Zyprexa Third-Party Payors class action, limited by the Supreme Court in *Bridge v. Phoenix Bond Indemnity Co.*, 128 S. Ct. 2131 (2008), and distinguished by the First Circuit Court of Appeals in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 582 F. 3d 156 (1st Cir. 2009).

a) Illustrations of the Individualized Proof Rule

A review of recent leading cases drawn from the federal circuits illustrates the nature of the intermediate appellate courts' concerns that underlie the Individualized Proof Rule.

The Court of Appeals for the Eight Circuit recently applied the Individualized Proof Rule in a case that offers some instructive points of comparison with the present case. *In re St. Jude Med., Inc.*, 522 F.3d 836 (8th Cir. 2008), concerned a class action on behalf of patients implanted

with "Silzone" prosthetic heart valves before the valves were recalled due to a finding of increased risk of paravalvular leakage. *Id.* at 837. Plaintiffs sought to recover damages from St. Jude Medical, the valves' manufacturer, under three Minnesota consumer protection statutes. The trial court certified the class, and the defendant manufacturer appealed, arguing that "adjudicating claims of liability for violating the statutes would require an inquiry into the causal relationship between any representation made by St. Jude and each plaintiff's injury," and that the damages and medical monitoring plaintiffs sought "also present numerous individual issues that make the case unsuitable for class certification." *Id.* at 838.

The appellate court agreed with defendant's arguments. In the course of reversing the certification order, it emphasized the role that treating physicians may have played as learned intermediaries in the selection of the Silzone valves:

> In a typical common-law fraud case, a plaintiff must show that he or she received the defendant's alleged misrepresentation and relied on it. *E.g., Breezy Point Airport, Inc. v. First Fed. Sav. and Loan Ass'n of Brainerd,* 288 Minn. 534, 179 N.W.2d 612, 615 (Minn. 1970). Because proof often varies among individuals concerning what representations were received, and the degree to which individual persons relied on the representations, fraud cases often are unsuitable for class treatment. *See* Fed. R. Civ. P. 23 advisory committee's note (discussing the 1966 Amendment to subdivision (b)(3): "[A]lthough having some common core, a fraud case may be unsuited for treatment as a class action if there was material variation in the representations made or in the kinds or degrees of reliance by the persons to whom they were addressed."); *Darms v. McCulloch Oil Corp.*, 720 F.2d 490, 493 (8th Cir.1983) (district court did not abuse discretion in refusing class certification where transactions were separate, and involved different representations and degrees of reliance); *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 745 (5th Cir.1996) ("[A] fraud class action cannot be certified when individual reliance will be an issue.").

This case exemplifies the difficulty with class treatment of cases alleging fraud or misrepresentation. St. Jude has presented evidence that a number of implant patients did not receive *any* material representation about the heart valve. Two of the five named plaintiffs, Levy Redden and Lester Grovatt, testified that they did not remember hearing anything about the unique qualities of the Silzone valve. On the other hand, one named plaintiff, Bonnie Sliger, testified that her doctor told her that the Silzone valve would be better because it would reduce the risk of infection. Whether each plaintiff even received a representation from St. Jude about the efficacy of the heart valve is likely to be a significant issue in each case of alleged liability.

Evidence of representations made to the treating physicians also illustrates the predominance of individual issues concerning representations and reliance. Physicians learned about St. Jude's heart valve in different ways. One doctor heard about the valve from a senior partner, another discovered it at a cardiology conference, and a third learned about the valve from a St. Jude sales representative and a St. Jude advertisement. Whether the information on which physicians based their actions ultimately can be traced to a representation by St. Jude undoubtedly will vary by individual physician. Even where the present record does contain evidence that a physician eventually talked to a St. Jude representative or read Silzone promotional materials, those physicians assert that they did not rely on the representations by St. Jude in deciding to recommend the Silzone valve to their patients. Any trial thus would require physician-by-physician inquiries into each doctor's sources of information about the valve, and the credibility of any physician's denial that he relied on St. Jude's statements.

. . .

Given the showing by St. Jude that it will present evidence concerning the reliance or non-reliance of individual physicians and patients on representations made by St. Jude, it is clear that resolution of St. Jude's potential liability to each plaintiff under the consumer fraud statutes will be dominated by individual issues of causation and reliance. The need for such plaintiff-by-plaintiff determinations means that common issues will not predominate the inquiry into St. Jude's liability.

> . . .
>
> The plaintiffs' effort to recover damages—alleged in the complaint to be "the cost of the medical care arising out of the use of the product together with any and all consequential damages recoverable under the law including, but not limited to, both past and future medical expenses, past wage loss, loss of future earning capacity, past and future pain, suffering, disability and emotional distress" —likewise would require individual determinations concerning the extent to which particular plaintiffs have suffered injuries caused by the Silzone valve.

522 F.3d at 838-39, 40, 41 (citations to documents in the record omitted).

The Individualized Proof Rule has been applied by other federal appellate courts faced with analogous questions of aggregate proof. *Fotta v. Trustees of United Mine Workers of Am.*, 319 F.3d 612 (3d Cir. 2003), for example, was a class action on behalf of miners who claimed interest on delayed disability payments. It was determined that class members were only entitled to interest if the delays could be shown to have been "wrongful." *Id.* at 619. Holding that this would require an individualized showing, the Court of Appeals for the Third Circuit rejected plaintiffs' class certification argument:

> Our holding that an ERISA beneficiary is entitled to interest only if the benefits were wrongfully withheld or wrongfully delayed requires us to conclude that the putative class members share no common issues of law or fact. To decide whether each putative class member would be entitled to interest, the District Court would have to determine whether the Fund wrongfully withheld or wrongfully delayed payment for each class member. The District Court would also have to determine the remedy for each class member, an individual determination. As we stated in *Holmes v. Pension Plan of Bethlehem Steel Corp.*, 213 F.3d 124 (3rd Cir.2000), a belief that "the interest entitlement of every class member can be calculated using a single, objective formula . . . ignores [*Fotta v. Trustees of United Mine Workers of Am. Health & Retirement Fund of 1974*, 165 F.3d 209 (3d Cir. 1998)] clear holding that interest on delayed ERISA benefits is an equitable remedy dependent upon the individual facts of each claim."

> [*Holmes*, 213 F.3d] at 137. Because both liability and the appropriate remedy must be determined for each plaintiff, no common issues of law or fact exist. We cannot, therefore, say that the District Court abused its discretion in denying class certification.

319 F.3d at 619.

Other decisions applying the Individualized Proof Rule have focused on injury to the individual as an element of plaintiffs' claims. *Doe v. Chao*, 306 F.3d 170 (4th Cir. 2002), was a class action on behalf of persons whose social security numbers were improperly publicly disclosed by the U.S. Department of Labor during adjudication of their claims for "black lung" benefits. Plaintiffs sought to eliminate individualized issues by seeking only the statutory minimum of $1,000 in damages for each class member. *Id.* at 183-84. The Court of Appeals for the Fourth Circuit, however, found that a statutory requirement that each class member demonstrate an actual "adverse effect" on him or her gave rise to individualized issues that precluded certification on typicality grounds:

> Appellants argue that the district court's denial of class certification was erroneous because, in their belated amendments to their complaints, they decided to pursue only the $1,000 minimum statutory damages, so that damages are in fact identical for all class members. If their amendments had been accepted, however, Appellants still would have faced grave typicality problems for two reasons. First, an adverse effect is a core liability requirement for a Privacy Act suit. The Act allows a private suit against an agency when the agency "fails to comply with any . . . provision of this section, or any rule promulgated thereunder, in such a way as to have an adverse effect on an individual . . . ." § 552a(g)(1)(D) (West 1996 & Supp. 2001). And second . . . the Act requires proof of actual damages to obtain a damage award. No Appellant in this case, other than Buck Doe, could even show an adverse effect, and Buck Doe was unable to demonstrate actual damages. Assuming that the claims of unnamed class members include a number of claims for which there is some evidence of adverse effect and actual damages, the putative class

> representatives have not suffered "injur[ies] similar to the injuries suffered by the other class members." *McClain v. South Carolina Nat'l Bank*, 105 F.3d 898, 903 (4th Cir.1997).

306 F.3d at 184.

The Individualized Proof Rule has been applied by the Court of Appeals for the Fifth Circuit, the circuit from which Mississippi's suit was transferred by the Judicial Panel on Multidistrict Litigation. *McManus v. Fleetwood Enters., Inc.*, 320 F.3d 545 (5th Cir. 2003), concerned a class action on behalf of motor home purchasers against a seller who had allegedly misrepresented the vehicles' towing capacity. The court noted that "[c]laims for money damages in which individual reliance is an element are poor candidates for class treatment, at best. We have made that plain." *Id.* at 549 (internal quotation marks and citation omitted). Individual questions of reliance were held to preclude class certification with respect to fraudulent inducement and negligent misrepresentation:

> Reliance will vary from plaintiff to plaintiff, depending on the circumstances surrounding the sale. For instance, Donnie McManus testified at his deposition that he read the wardrobe door tag and asked the salesperson about the towing capacity. June McManus testified that she did not read the tag, nor did she draw any conclusion as to whether the motor home would be able to tow a Jeep Cherokee. The individual reliance issues are apparent even as between the two representative plaintiffs. Other potential class members certainly may have read the wardrobe door tag as Fleetwood reads it—as being silent on the issue of supplemental brakes—and certainly some class members may have actually *known* at the time of purchase that supplemental brakes would be needed. At this point in the litigation, the McManuses have failed to show that these potential variables are sufficiently uniform to justify class treatment . . . .

320 F.3d at 550.

The *McManus* court's holding was grounded in its own precedent. In *Brolin v. Sears, Roebuck & Co.*, 231 F.3d 970 (5th Cir. 2000), a class action on behalf of more than one million bankrupt debtors alleging illegal post-bankruptcy collection practices by Sears, the court held that "individual findings of reliance necessary to establish RICO [fraud] liability and damages preclude" certification under both Rules 23(b)(2) and (b)(3). *Id.* at 978. *Cimino v. Raymark Indus., Inc.*, 151 F.3d 297 (5th Cir. 1998), was a quasi-class action. It consolidated over 3,000 individual cases against manufacturers of products containing asbestos. *Id.* at 311-19. The appellate court disapproved of a trial plan according to which causation and damages were determined for all plaintiffs based on extrapolation from the results of representative trials of small subsets of the consolidated claims. It was held that "under Texas personal injury products liability law causation and damages are determined respecting plaintiffs as individuals, not groups." *Id.* at 313 (internal quotation marks omitted). The court noted that, with only one exception, "we are aware of no appellate decision approving such a group, rather than individual, determination of cause in a damage suit for personal injuries to individuals at widely different times and places." *Id.* at 316. Similarly, in *Castano v. Am. Tobacco Co.*, 84 F. 3d 734 (5th Cir. 1996), a class action on behalf of smokers against cigarette manufacturers, the trial court's decision to certify the class was reversed because "a fraud class action cannot be certified when individual reliance will be an issue." *Id.* at 745.

The Court of Appeals for the Seventh Circuit has taken the same position as the Fifth Circuit's Court of Appeals regarding certification of fraud class actions. *Oshana v. Coca-Cola Co.*, 472 F.3d 506 (7th Cir. 2006), concerned a class action on behalf of drinkers of fountain Diet Coke. It was alleged that differences between fountain and bottled versions of the soft drink—

namely, that the fountain version, unlike the bottled version, contained saccharine—had been wrongfully withheld from consumers. The court held that individual issues of reliance and causation precluded certification:

> The district court determined that the proposed class was not sufficiently definite to warrant class certification. Oshana sued Coke for violating the ICFA [the Illinois consumer protection law] and for unjust enrichment. To prevail on a claim for damages under the ICFA, Oshana and her fellow class members must prove: (1) a deceptive act or practice by Coke; (2) that the act or practice occurred in the course of conduct involving trade or commerce; (3) that Coke intended Oshana and the members of the class to rely on the deception; and (4) that actual damages were proximately caused by the deception. *Avery v. State Farm Mut. Auto. Ins. Co.*, 216 Ill. 2d 100, 296 Ill. Dec. 448, 835 N.E. 2d 801, 850 (Ill. 2005); *Oliveira v. Amoco Oil Co.*, 201 Ill. 2d 134, 267 Ill. Dec. 14, 776 N.E. 2d 151, 164 (Ill. 2002). In other words, a damages claim under the ICFA requires that the plaintiff was deceived in some manner and damaged by the deception. *Oliveira*, 267 Ill. Dec. 14, 776 N.E. 2d at 164 ("*Zekman [v. Direct Am. Marketers*, 182 Ill. 2d 359, 231 Ill. Dec. 80, 695 N.E. 2d 853 (Ill. 1998),] makes clear that, to properly plead the element of proximate causation in a private cause of action for deceptive advertising brought under the Act, a plaintiff must allege that he was, in some manner, deceived.").
>
> Membership in Oshana's proposed class required only the purchase of a fountain Diet Coke from March 12, 1999, forward. Such a class could include millions who were not deceived and thus have no grievance under the ICFA. Some people may have bought fountain Diet Coke *because* it contained saccharin, and some people may have bought fountain Diet Coke *even though* it had saccharin. Countless members of Oshana's putative class could not show any damage, let alone damage proximately caused by Coke's alleged deception. *See Oliveira*, 267 Ill. Dec. 14, 776 N.E.2d at 164 (holding that those who "knew the truth" do not have valid ICFA claims because they cannot claim to have been deceived).

472 F.3d at 513-514.

As in *Oshana, St. Jude*, and similar cases, the element of reliance was a focus of the court in *Poulos v. Caesars World, Inc.*, 379 F.3d 654 (9th Cir. 2004), a class action on behalf of gamblers against casinos offering video poker and electronic slot machines. Plaintiffs alleged that defendants had fraudulently manipulated players' beliefs about the operation of the machines and the odds of winning on any particular play. *Id.* at 659. The Court of Appeals for the Ninth Circuit noted that the case offered an "opportunity to clarify the extent to which a class action plaintiff must establish individualized reliance to meet the causation requirement of a civil [RICO] claim predicated on mail fraud—an issue that bears heavily on a plaintiff's ability to meet the predominance and superiority requirements of class certification under Federal Rule of Civil Procedure 23(b)(3)." *Id.* at 658. The court found that the individualized proof requirement precluded certification of the class:

> We conclude that the Class Representatives, like all plaintiffs asserting civil RICO claims, must prove individualized reliance where that proof is otherwise necessary to establish actual or proximate causation. Because the district court did not abuse its discretion in determining that individualized causation issues would predominate in this case, and no presumption of reliance applies, we affirm the denial of class certification.
>
> . . .
>
> The misrepresentations standing alone have little legal significance. To connect the dots between the bare allegations and the injury, the class needs something more. Here, reliance provides a key causal link between the Casinos' alleged misrepresentations and the Class Representatives' injury. For example, the Class Representatives allege that "[v]ideo poker machines are designed in their appearance and labeling and represented and advertised to the public as replicating random shuffling of a standard . . . deck . . . followed by a deal and a draw from such a deck," when in fact the machines do not use cards and do not operate in the manner of a card game. Even taking the Class Representatives' allegations as true, however, and assuming that all plaintiffs in the proposed classes suffered financial loss or other concrete injury as a consequence of playing the machines, it

does not necessarily follow that plaintiffs' injuries are causally linked to the Casinos' alleged misrepresentations. In this case, individualized reliance issues related to plaintiffs' knowledge, motivations, and expectations bear heavily on the causation analysis.

Due to the unique nature of gambling transactions and the allegations underlying the class claims, this is not a case in which there is an obvious link between the alleged misconduct and harm. Rather, linking the Casinos' alleged misrepresentations to plaintiffs' losses requires forging a chain of inferences that, viewed together, amount to individualized reliance.

Instead of treating this proposition in the abstract, it is instructive to illustrate the point with some concrete examples of how a claim might play out. A plaintiff claiming that the Casinos' misrepresentations caused her to play electronic slot machines and suffer losses must do more than merely allege causation; she must draw a causal link between the alleged fraud and the alleged harm. The plaintiff might draw this link by proving that the Casinos' failure to inform players that the electronic slot machines operate differently than their mechanical counterparts affected her decision to play, or that she was influenced by the fact that electronic slot machines look like traditional slot machines. In turn, this would require her to establish that she was aware of how the mechanical slot machines operated, was unaware that the electronic slot machines operated differently than those machines, and was motivated to play the electronic slot machine based on her knowledge of these factors. Similarly, a plaintiff alleging losses stemming from misrepresentations related to the video poker machines might draw a causal link by establishing that she was an ace player in the traditional table poker game and played the video poker game, at least in part, because she was misled into believing that the video poker and table poker games functioned similarly and offered the same odds. It is not enough to say, "I played the games and I lost money," or "I didn't make any money."

What these examples make clear is the rather obvious point that gambling is not a context in which we can assume that potential class members are always similarly situated. Gamblers do not share a common universe of knowledge and expectations—one motivation does not "fit all." Some players may be unconcerned with the odds of winning, instead engaging in casual gambling as entertainment or a social activity. Others may have played with absolutely no knowledge or information regarding the odds of winning such that the appearance and labeling of the machines is irrelevant and did nothing to influence their

> perceptions. Still others, in the spirit of taking a calculated risk, may have played fully aware of how the machines operate. Thus, to prove proximate causation *in this case,* an individualized showing of reliance is required.
>
> Because it is neither necessary nor prudent to reach the issue of whether reliance is the *only way* plaintiffs can establish causation in a civil RICO claim predicated on mail fraud, we decline to do so. Rather, we note that our holding is both narrow and case-specific, and that we have been careful to frame the controlling issue in terms of causation, not reliance.

379 F.3d at 658, 665-66 (footnotes omitted).

The Court of Appeals for the Eleventh Circuit followed the lead of the Fifth's Circuit's *Bolin* decision, and applied the Individualized Proof Rule in *Heffner v. Blue Cross & Blue Shield of Ala., Inc.*, 443 F.3d 1330 (11th Cir. 2006), a class action on behalf of hundreds of thousands of participants and beneficiaries of group health plans who claimed that they were charged a calendar year deductible despite a Summary Plan Document ("SPD") which stated that there were no such deductibles. *Id.* at 1333. The court held that "to prevail each plaintiff must prove reliance on the SPD"; individualized issues therefore precluded certification:

> As we have just explained, in order to be entitled to relief each class member must prove that he relied on the no deductible term of his plan's SPD where the other plan documents do provide that there is a calendar year deductible. In a variety of contexts, we have held that the reliance element of a class claim presents problems of individualized proof that preclude class certification. *See, e.g., Sikes v. Teleline, Inc.*, 281 F.3d 1350, 1361-63 (11th Cir. 2002) (reversing Rule 23(b)(3) class certification of a civil RICO claim in part because the district court erred in presuming reliance); *Andrews v. Am. Tel. & Tel. Co.*, 95 F.3d 1014, 1023-24 (11th Cir. 1996) (reversing certification of a Rule 23(b)(3) class action asserting mail and wire fraud claims on grounds of unmanageability in part because each plaintiff would be required to prove reliance which meant that the claims were "not wholly subject to class-wide resolution"); *Hudson v. Delta Air Lines, Inc.*, 90 F.3d 451, 457 (11th Cir. 1996) (affirming denial of class certification based on lack of commonality prerequisite of Rule

23(a)(2) because reliance element of ERISA claims was "not susceptible to class-wide proof"). Although this Court has not determined that individual reliance issues weigh against Rule 23(b)(2) certification, the Fifth Circuit has. *See Bolin v. Sears, Roebuck & Co.*, 231 F.3d 970, 978 (5th Cir.2000) (concluding that "individual findings of reliance necessary to establish RICO liability and damages preclude ... (b)(2) certification"). We agree with the *Bolin* decision.

Even if Heffner proves that he purchased prescription drugs in reliance on the Funding Plus SPD's calendar year deductible provision, only he will be entitled to relief on that proof. Other class members will not. "[F]inal injunctive relief or corresponding declaratory relief with respect to the class as a whole" would not be warranted. *See* Fed. R. Civ. P. 23(b)(2); *see also Jones v. Am. Gen. Life & Accident Ins. Co.*, 213 F.R.D. 689, 702 (S.D. Ga. 2002) (refusing to certify class under Rule 23(b)(2) "[b]ecause each individual's reliance would be in question" and "there would be no way to say with any certainty that the same relief would be appropriate for all class members").

As we have explained, "the claims contemplated in a (b)(2) action are *class* claims, claims resting on the same grounds and applying more or less equally to all members of the class." *Holmes v. Continental Can Co.*, 706 F.2d 1144, 1155 (11th Cir. 1983). Moreover, the forms of relief available in Rule 23(b)(2) class actions are in the nature of group remedies that benefit the entire class. *See Cooper*, 390 F.3d at 720 ("the basic premise of . . . a [Rule 23(b)(2)] class action [is] that class members suffer a common injury properly addressed by class-wide equitable relief"); *Murray*, 244 F.3d at 812 (vacating Rule 23(b)(2) class certification because plaintiffs' claim for compensatory damages predominated over class' claim for equitable relief where plaintiffs "[did] not seek damages as a group remedy" but "[i]nstead . . . [sought] damages as a remedy for their alleged individual pain and suffering") (quotation marks and citations omitted); *Holmes*, 706 F.2d at 1155 n.8 ("Injuries remedied through (b)(2) actions are really group, as opposed to individual injuries.") (quotation marks and citation omitted). Certification under Rule 23(b)(2) is proper when the relief sought necessarily affects all class members. *See Holmes*, 706 F.2d at 1157.

Success by the class representative in this case, however, will not result in relief to other class members. That is because, in order to be entitled to the relief that the class seeks, each plaintiff must prove reliance on the SPD of his or her plan. Injunctive or declaratory relief, and any other equitable relief based on it, will

> not automatically flow to the class "as a whole" even if Heffner succeeds in proving reliance on his SPD. Accordingly, we hold that it was an abuse of discretion to certify under Rule 23(b)(2) the plaintiffs' ERISA claims seeking individualized relief for Blue Cross' imposition of the calendar year deductibles. *Cf. In re Elec. Data Sys. Corp. "ERISA" Litig.*, 224 F.R.D. 613, 629 (E.D.Tex.2004) (certifying ERISA breach of fiduciary duty class action brought on the plan's behalf under Rule 23(b)(2) because "monetary relief will go to the Plan itself" and "is in the nature of a group remedy").

443 F.3d at 1344-45.

b) Statistical Evidence and the *McLaughlin* Decision

Like some other federal appellate courts, the Court of Appeals for the Second Circuit has largely rejected the use of aggregate proof to show reliance, loss causation, or injury in mass tort cases. *See McLaughlin*, 522 F.3d at 223-30. While Mississippi substantive law governs Mississippi's claims, orders of this court in MDL matters are appealed to the Court of Appeals for the Second Circuit. *See* Part IV.B, *supra.* The Court of Appeals may be expected to view issues of statistical aggregate evidence through the lens of its own case law, which appears to be among the most detailed and well-developed on this point of any jurisdiction, including the State of Mississippi and the Fifth Circuit. It appears in any case that the Fifth Circuit Court of Appeals is inclined to be at least as restrictive in its approach to aggregate proof in mass tort cases as is the Second Circuit. *See* Part IV.E.1.a, *supra* (discussing, *e.g.*, *McManus*, 320 F.3d at 549); *see also* John C. Coffee, Jr. & Daniel Wolf, Class Certification: Developments Over the Last Five Years 2004-2009, 10 Class Action Litig. Rep. (BNA) No. 10., at S-47 (Special Report, Nov. 13, 2009) ("[T]he relevant standards [for class certification] appear to be varying with the Circuit, with the Second, Third, and Ninth Circuits taking a more liberal stance than the other Circuits, *while the Fourth and Fifth Circuits generally seem the most conservative*." (emphasis added)).

In *McLaughlin*, the Court of Appeals for the Second Circuit reversed the trial court's decision, in *Schwab v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 992 (E.D.N.Y. 2006), to certify a class of smokers who alleged that cigarette manufacturers had deceived the public as to the healthier quality of light cigarettes. The trial court had found that plaintiffs could prove reliance on a class-wide basis using statistical methods of analysis applied to determine the effects of defendant's nationwide campaign to promote light cigarettes.

That theory was rejected on appeal. An appellate panel of the Second Circuit reviewing *Schwab* invoked the Individualized Proof Rule as follows:

> [P]roof of misrepresentation—even widespread and uniform misrepresentation—only satisfies half of the equation; the other half, reliance on the misrepresentation, *cannot be the subject of general proof.* Individualized proof is needed to overcome the possibility that a member of the purported class purchased Lights for some reason other than the belief that Lights were a healthier alternative—for example, if a Lights smoker was unaware of that representation, preferred the taste of Lights, or chose Lights as an expression of personal style.

522 F.3d at 223 (emphasis added).

The appellate court considered but rejected plaintiffs' attempt to invoke a fraud-on-the market presumption (relied upon in securities cases to avoid the Individualized Proof Rule) to show that manufacturers' misrepresentations "distorted the body of public information and that, in purchasing Lights [*i.e.*, light cigarettes], plaintiffs relied upon the public's general sense that Lights were healthier . . . whether or not individual plaintiffs were actually aware of" the misrepresentations. *Id.* at 223-24. Emphasized by the reviewing court was the fact that the consumer market in light cigarettes was not the type of efficient securities market to which the fraud-on-the-market presumption is well suited. *Id.* at 224. The fact that the market price of

cigarettes appeared to be unresponsive to relevant information was fatal to plaintiffs' argument that a presumption of reliance should apply:

> Plaintiffs and the district court suggest that defendants distorted the body of public information and that, in purchasing Lights, plaintiffs relied upon the public's general sense that Lights were healthier than full-flavored cigarettes, whether or not individual plaintiffs were actually aware of defendants' alleged misrepresentation. *Cf. Falise v. Am. Tobacco Co.*, 94 F. Supp. 2d 316, 335 (E.D.N.Y.2000) ("Where . . . the fraudulent scheme is targeted broadly at a large proportion of the American public[,] the requisite showing of reliance is less demanding. Such sophisticated, broad-based fraudulent schemes by their very nature are likely to be designed to distort the entire body of public knowledge . . ."). Their argument invokes the fraud-on-the-market presumption set forth in *Basic Inc. v. Levinson*, 485 U.S. 224[, 108 S.Ct. 978, 99 L.Ed.2d 194] (1988), which concerned fraud claims in the securities context. "The fraud-on-the market doctrine . . . creates a rebuttable presumption that (1) misrepresentations by an issuer affect the price of securities traded in the open market, and (2) investors rely on the market price of securities as an accurate measure of their intrinsic value." *Hevesi v. Citigroup Inc.*, 366 F.3d 70, 77 (2d Cir.2004). Thus, a plaintiff alleging securities fraud may establish reliance simply by virtue of the defendant's public dissemination of misleading information. *See Basic*, 485 U.S. at 241-42[, 108 S.Ct. 978] (noting that because the price of stock in an efficient market reflects all publicly available information, "[m]isleading statements will . . . defraud purchasers of stock even if the purchasers do not directly rely on the misstatements").
>
> We do not think that the *Basic* presumption, or the district court's variation of it, applies in this case; we cannot assume that, regardless of whether individual smokers were aware of defendants' misrepresentation, the market at large internalized the misrepresentation to such an extent that all plaintiffs can be said to have relied on it. *Basic* involved an efficient market-the market in securities traded on the New York Stock Exchange-capable of rapidly assimilating public information into stock prices, *see id.* at 247, 249 n. 29[, 108 S.Ct. 978] (describing the securities market as "impersonal, well-developed," and "information-hungry"); the market for consumer goods, however, is anything but efficient, *cf. Sikes v. Teleline, Inc.*, 281 F.3d 1350, 1364 (5th [11th] Cir.2002) ("[E]ach individual plaintiff is the only person with information

> about the content of the advertisement upon which he relied."). Indeed, *the fact that the publication of Monograph 13 produced no change in either the sales or the price of Lights shows just how unresponsive the consumer market in Light cigarettes is to the advent of new information. See In re IPO,* 471 F.3d at 43 ("Plaintiffs' own allegations as to how slow the market was to correct the alleged price inflation despite what they also allege was widespread knowledge of the scheme indicate the very antithesis of an efficient market."). As we stated in *In re [Initial Public Offering Sec. Litig.*, 476 F.3d 24 (2d Cir. 2006)], "[w]ithout the *Basic* presumption, individual questions of reliance would predominate over common questions." *Id.; see also Gunnells,* 348 F.3d at 435 (noting that *Basic's* presumption of actual reliance was based on the efficiency of capital markets, which did not apply to plaintiffs' purchase of health care plans, and that therefore actual reliance could not be presumed and individualized inquiry was required).

522 F.3d at 233-34 (emphasis added, footnote omitted); *see id.* at 226 ("Indeed, the fact that the market did not shift away from light cigarettes after the publication of Monograph 13 is compelling evidence that plaintiffs had other, non-health related reasons for purchasing Lights.").

In the absence of convincing evidence of overpricing, which might have supported a *Basic* presumption, plaintiffs' aggregate proof of reliance was held insufficient. The *McLaughlin* court applied the same reasoning to issues of loss causation and injury, finding that "the issue of loss causation, much like the issue of reliance, cannot be resolved by way of generalized proof," *Id.* at 226, and that "out-of-pocket losses cannot be shown by common evidence because they constitute an inherently individual inquiry." *Id.* at 228. In reaching the latter conclusion, the court specifically rejected use of a "loss of value theory"—the statistical methodology employed by plaintiff's expert Dr. Rosenthal on behalf of both the Third-Party Payors and the State of Mississippi. *Id.* at 227-30.

McLaughlin has been partially abrogated by the Supreme Court's subsequent decision in *Bridge v. Phoenix Bond & Indem. Co.*, 128 S.Ct. 2131 (2008), but only with respect to *McLaughlin's* interpretation of the federal civil racketeering statute, not to its rejection of statistical evidence or the loss-of-value methodology. *McLaughlin* had held that "[i]n cases . . . when mail or wire fraud is the predicate act for a civil RICO claim, the transaction or 'but for' causation element requires the plaintiff to demonstrate that he relied on the defendant's misrepresentation." 522 F.3d at 222. *Bridge* rejected this reading of the statute, holding that "a plaintiff asserting a RICO claim predicated on mail fraud need not show, either as an element of its claim or as a prerequisite to establishing proximate causation, that it relied on the defendant's alleged misrepresentations." 128 S.Ct. at 2145. The upshot of this holding was that the *Bridge* plaintiffs could establish their RICO claims by showing that they were injured as a result of a third party's reliance—rather than their own reliance—on the alleged misrepresentations. *Id.* at 2144-45. *Bridge* did not involve injuries to a class or to a large, diffuse population, and did not address the use of aggregate proof to show reliance, loss causation, or injury.

In mass tort cases decided prior to *McLaughlin*, the Court of Appeals for the Second Circuit had also cast doubt on the use aggregate proof. In *Blue Cross & Blue Shield of New Jersey, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 211, 228 (2d Cir. 2003), the court certified to the New York Court of Appeals the question of whether "individualized proof of harm to subscribers [is] required when a third party payer of health care costs seeks to recover costs of services provided to subscribers" as a result of violations of New York's consumer protection law. On return of the case from the New York Court of Appeals, the Court of Appeals for the Second Circuit ordered the case dismissed on other grounds, effectively negating the trial court's

position allowing proof on critical issues by aggregate evidence. *See Empire Healthchoice, Inc. v. Philip Morris USA Inc.*, 393 F.3d 312 (2d Cir. 2004); *see also* Coffee & Wolf, *supra*, at S-32 to S-33 ("A few cases have been prepared to dispense with individualized proof of reliance based on state law grounds, but their status on appeal is uncertain." (citing *Blue Cross & Blue Shield of New Jersey, Inc. v. Philip Morris USA, Inc.*, *supra*)). The *Blue Cross* case was particularly striking because a jury had used aggregate proof and statistical analysis to arrive at a relatively modest verdict for the plaintiff in a structural class action. *See Blue Cross and Blue Shield of New Jersey, Inc. v. Philip Morris USA, Inc.*, 178 F. Supp. 2d 198 (E.D.N.Y. 2001).

In *In re Simon Litigation II*, 407 F.3d 125, 140 (2d Cir. 2005), another tobacco case, the appellate court noted, without deciding, the question whether "the district court's proposed statistical aggregation of proof, or its invocation of the 'fraud-on-the-market' theory, would have been appropriate for class-wide approximation of compensatory liability . . . , or for proof of any given element going toward actual liability in a conventional class action for compensatory and punitive damages."

These decisions, together with *McLaughlin*, suggest that the Court of Appeals for the Second Circuit's skepticism about the utility of aggregate proof, and in particular statistical evidence, in obtaining justice for large numbers of mulcted individuals applies across-the-board to all types of cases not involving securities fraud. These decisions in effect rejected any fluid recovery theory to avoid the problems posed by the need for individualized proof of damages. *Cf. In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d 179, 184 (2d Cir. 1987) (allowing use of portion of settlement fund "to provide programs for the class as a whole"); *In re Fresh Del Monte Pineapples Antitrust Litig.*, No. 1:04-MD-1628, 2008 WL 5661873 at *6-7 (S.D.N.Y.

Feb. 20, 2008) (rejecting fluid class recovery because price reduction would not necessarily benefit injured purchaser class).

The *McLaughlin* court's analysis has influenced subsequent decisions. For instance, *In re Neurontin Marketing, Sales Practices, and Liab. Litig.*, 257 F.R.D. 315, 322-27 (D. Mass. 2009), concerned a class action on behalf of patients and third-party payors against the manufacturer of Neurontin, an epilepsy drug. It was alleged that the defendant improperly marketed Neurontin for off-label uses. *Id.* at 316-17. After a thoughtful and thorough discussion of the significance of *McLaughlin*, *St. Jude*, and related Individualized Proof Rule cases, class certification was denied on predominance grounds because individualized issues of reliance and causation overwhelmed common questions. *Id.* at 322-33. The court considered but rejected the use of statistical evidence provided by Dr. Rosenthal—the same expert relied upon by the Third-Party Payors and Mississippi in the Zyprexa cases. *Id.* at 327-31. *See also Gutierrez v. Wells Fargo & Co.*, No. C 07-05923, 2009 WL 1247040, at *4-5 (N.D. Cal. May 5, 2009).

One important decision has distinguished *McLaughlin*. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 582 F.3d 156 (1st Cir. 2009), concerned a class action on behalf of patients and third party payors who purchased AstraZeneca's prostate-cancer drug Zoladex. Plaintiffs alleged that the Average Wholesale Price (AWP) of Zoladex published by AstraZeneca, which was used to calculate reimbursements and patient co-payments, did not reflect discounts and rebates offered to physician providers. The providers therefore reaped the windfall of the difference between the AWP and the actual price, and AstraZeneca marketed Zoladex to physicians on this basis. *See* 582 F.3d at 160-61. After a bench trial, AstraZeneca was found liable for unfair and deceptive business practices under Massachusetts consumer

protection law. *Id.* AstraZeneca appealed, arguing, among other things, that the trial court had erred by considering the knowledge of only the named plaintiffs, and by relying on an aggregate, statistical damages methodology. *Id.* at 194-95, 197.

The appellate court rejected these challenges, finding that the individualized issues identified by AstraZeneca were not sufficiently significant to undermine the district court's decision. The Court of Appeals for the Second Circuit's *McLaughlin* decision and Court of Appeals for the Fifth Circuit's *Cimino* decision were specifically considered and distinguished. *See* Part IV.E.1.a *supra*. It was held that the district court had considered the potentially individualized issues with sufficient care to reasonably reach aggregate conclusions with respect to the entire class. The court emphasized that it is in the very nature of a class action to require a certain amount of aggregation and extrapolation. Because the reasoning of the First Circuit Court of Appeals seems so persuasive, it is set out at length below:

> B. Absent Class Members
>
> The gravamen of AstraZeneca's second challenge to the class-wide judgment is its contention that the district court erred in addressing only the knowledge of the named class representatives, particularly BCBS-MA, when examining the TPPs' knowledge and expectations as to AWP inflation. Pointing to the "fact-specific" nature of the district court's analysis of the class representatives' knowledge and expectations, AstraZeneca argues that the district court should also have analyzed—and permitted discovery and inquiry by AstraZeneca into—the knowledge and expectations of absent class members, who AstraZeneca maintains may have had more knowledge than BCBS-MA did of Zoladex pricing. After all, the argument runs, even if BCBS-MA lacked sufficient knowledge of AWP inflation and Zoladex pricing, there is reason to believe that other, absent class members could have had more refined knowledge and expectations than the class representatives did, for at least some of the absent class members were large and sophisticated TPPs who had been directly offered discounts on Zoladex by AstraZeneca through various cost-reduction programs.

Thus, AstraZeneca argues that because the actual knowledge and expectations of the absent class members was never established, the district court "excused [them] from having to establish each element of their Chapter 93A claims," thereby "den[ying] AstraZeneca its right to defend itself."

This argument, of course, is a familiar one in the context of class action lawsuits. It is beyond question that, under some circumstances, constitutional principles prohibit a court from relying on proof relating to the class representatives to make class-wide findings. But it is equally obvious that class-action litigation often *requires* the district court to extrapolate from the class representatives to the entire class; for example, the district court employed just this kind of analysis without objection in this very case when it applied the "discovery rule" to determine when the statute of limitations should cut off the plaintiffs' claims, but did not make specific findings as to each class member, *In re Pharm.*, 491 F.Supp.2d [20], 75-80 [(D. Mass 2007]. *See also Hansberry v. Lee,* 311 U.S. 32, 42-43, 61 S.Ct. 115, 85 L. Ed. 22 (1940) ("It is familiar doctrine of the federal courts that members of a class not present as parties to the litigation may be bound by the judgment where they are in fact adequately represented by parties who are present, or where they actually participate in the conduct of the litigation in which members of the class are present as parties, or where the interest of the members of the class, some of whom are present as parties, is joint, or where for any other reason the relationship between the parties present and those who are absent is such as legally to entitle the former to stand in judgment for the latter." (citations omitted)). The district court in this case determined that the class was adequately represented when it certified the class, and it carefully examined the representatives' knowledge and expectations as to spreads. As a general matter, this is precisely the kind of analysis that Rule 23 was designed to permit, and it would quickly undermine the class-action mechanism were we to find that a district court presiding over a class action lawsuit errs every time it allows for proof in the aggregate.

More specifically, the district court's aggregate determination as to knowledge and expectations was permissible and appropriate for two reasons. First, AstraZeneca and the other Track 1 defendants were allowed ample opportunity to depose TPPs prior to trial-in all, these defendants deposed roughly fifty TPPs, and multiple representatives from many of those. Despite this extensive discovery, AstraZeneca marshals no specific evidence on appeal to suggest that absent class member TPPs had

knowledge or expectations that differed substantially from class representative BCBS-MA.

Instead, AstraZeneca states, without record citation, that "many other payers" were as sophisticated as BCBS-MA, and that unnamed TPPs who "fully understood that AWPs were not predictably related to acquisition costs or who understood the pricing of Zoladex itself were permitted to recover." Yet the portions of the record to which AstraZeneca cites to raise the specter of individualized differences in knowledge and expectations among the class members in fact demonstrate the class members' similarities, for the record citations contain evidence that the class-member TPPs were offered the same opportunities to take advantage of discounts and rebates that BCBS-MA was offered. If these portions of the record suggest anything, it is that, contrary to AstraZeneca's position, BCBS-MA was a good proxy for the class members' knowledge and expectations.

Second, the district court's conclusions about industry knowledge and expectations were based on a careful analysis of the class representatives and on expert testimony that was properly admitted, and therefore it did not exhibit any of the evils paraded in AstraZeneca's brief with references to cases such as *Broussard v. Meineke Discount Muffler Shops, Inc.*, 155 F.3d 331, 343 (4th Cir.1998) (reliance on a fictitious, composite plaintiff "divorced from any actual proof of damages" whereas North Carolina law required "reasonable certainty" about lost profits awards), *Western Electric Company v. Stern,* 544 F.2d 1196 (3d Cir. 1976) (unduly limited discovery), and *Cimino v. Raymark Industries, Inc.*, 151 F.3d 297 (5th Cir.1998) (extrapolating damages from personal injuries and death from a set of sample cases).

Nor are we persuaded that this case has individualized circumstances similar to those at issue in *McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir.2008), where the Second Circuit cast doubt on the use of common proof to establish reliance and causation among a class of smokers who had purchased "light" cigarettes over a thirty-seven year period. In that case, the Second Circuit expressed its concern that the class-member consumers may have chosen the product for a variety of reasons, such as personal preference, unrelated to the alleged misrepresentations implied in the term "light." *Id.* at 225-26 ("[E]ach plaintiff in this case could have elected to purchase light cigarettes for any number of reasons, including a preference for the taste and a feeling that smoking Lights was 'cool.'"). Here, however, we harbor no such concerns about intractably payor-specific issues. The evidence in

the record relating to the knowledge and expectations about AWP inflation and Zoladex pricing among TPPs is voluminous, and as noted above, the portions of the record cited by AstraZeneca as cause for concern contain strikingly consistent evidence as to each of the TPPs. We thus are not persuaded that the evidence of variation across the class members as to their knowledge and expectations about AWP inflation and Zoladex pricing demonstrates the existence of significant individualized issues in the first place, much less variations so significant as to raise concerns of a constitutional dimension.

C. Aggregate Damages

AstraZeneca's third challenge to the entry of a class-wide judgment is that the district court awarded aggregate damages "without *any* individualized determination of damages as to a single class member (including the named plaintiffs)," thereby violating AstraZeneca's "fundamental right" to defend against each class member's claim of injury and damages. In support of its argument that a "rough estimate" of damages is insufficient, AstraZeneca cites *In re New Motor Vehicles Canadian Export Antitrust Litigation,* 522 F.3d 6, 28 (1st Cir.2008), and *McLaughlin,* 522 F.3d 215, for the proposition that the plaintiffs should have been required to prove that each class member was harmed by AstraZeneca's pricing practices. Requiring such proof, the company argues, ensures that AstraZeneca will pay damages reflective of its actual liability.

As to whether the plaintiffs adequately proved the class members' claims of injury, AstraZeneca once again takes aim at Dr. Hartman's methodology, arguing that the approach he used to set the 30% liability speed limit failed to take into account the individualized circumstances of the class members. Little more need be said about Dr. Hartman's liability analysis or the district court's decision to adopt it. Suffice it to say that the methodology used to develop the 30% "speed limit" that triggered potential liability, which included an examination of TPPs' (including class representative BCBS-MA's) testimony, data, and contracts, sufficiently incorporated individualized information about the class members to support the district court's decision to adopt it for the entire class.

AstraZeneca's criticisms of Dr. Hartman's damages calculation, however, merit further discussion. AstraZeneca alleges that Dr. Hartman's calculation fails to account for five factors: i) that fourteen Massachusetts TPPs and 23,000 consumers

> opted out of the class; ii) that those persons with flat co-payments were defined out of the class; iii) that some TPPs did not always reimburse based on AWP during the class period; iv) that some physicians did not bill patients for the co-payments; and v) that some physicians did not collect the co-payments that were billed. AstraZeneca asks us to review the district court's damages methodology for a violation of the company's due process rights, and of Federal Rule of Civil Procedure 23.
>
> The use of aggregate damages calculations is well established in federal court and implied by the very existence of the class action mechanism itself. *See, e.g.*, 3 Herbert B. Newberg & Alba Conte, *Newberg on Class Actions* § 10.5, at 483-86 (4th ed. 2002) ("Aggregate computation of class monetary relief is lawful and proper. Courts have not required absolute precision as to damages. . . . Challenges that such aggregate proof affects substantive law and otherwise violates the defendant's due process or jury trial rights to contest each member's claim individually, will not withstand analysis.... Just as an adverse decision against the class in the defendant's favor will be binding against the entire class in the aggregate without any rights of individual class members to litigate the common issues individually, so, too, an aggregate monetary liability award for the class will be binding on the defendant without offending due process." (footnotes omitted)). There is nothing about this case to suggest a contrary conclusion. Thus, to the extent that AstraZeneca argues that the district court's decision to use an aggregate damages methodology violated Rule 23 or the company's due process rights, AstraZeneca's challenge fails in the starting gate.

582 F.3d at 194-98 (footnotes omitted).

The reasoning of the Court of Appeals for the First Circuit in *In re Pharmaceutical Industry Average Wholesale Price Litigation* is significant in that it highlights the tensions between the Individualized Proof Rule and the underlying rationale for Rule 23, and for aggregate litigation in general, of seeking justice for the many. *But see In re Pharmaceutical Industry Average Wholesale Price Litigation*, 252 F.R.D. 83, 96-99 (D. Mass. 2008) (in related nationwide class action portion of AWP litigation, granting certification only with respect to claims brought under state consumer protection laws that did not require showing of reliance, but

applying *McLaughlin* to deny certification with respect to state consumer protection laws that did require such a showing). It is apparent that there is uncertainty regarding the kinds of factual circumstances that may justify exceptions to the Individualized Proof Rule.

An observation regarding the force of *In re Pharmaceutical Industry Average Wholesale Price Litigation* in considering the present case is merited. The Court of Appeals for the First Circuit emphasized that factual inquiries into the circumstances that might have differentiated class members had revealed little significant difference between them. For example, despite having deposed representatives of some fifty third-party payor class members, AstraZeneca had been unable to marshal "specific evidence on appeal to suggest that absent class member [third-party payors] had knowledge or expectations that differed substantially from [the] class representative." 582 F.3d at 196.

Having overseen thousands of Zyprexa-related cases in this MDL, this court is familiar with the many factual differences which may distinguish the situations of individual Mississippi patients and treating physicians from one another. As indicated in its Third-Party Payor class action decision, discussed immediately below, based on its experience with the Zyprexa litigations, this court concluded that proof on a statistical and analytical basis was appropriate despite differences among individual Zyprexa patients.

To the extent that *In re Pharmaceutical Industry Average Wholesale Price Litigation* is in conflict with other circuits' case law concerning the Individualized Proof Rule, it has no ruling authority here. Yet the power of its analysis and the continuing need to find a procedurally convenient and fair way to try these kinds of mass product liability cases—deterring the guilty

and compensating the many injured—warrants further consideration rather than unthinking rejection based solely on precedent.

2. Zyprexa Third-Party Payors Certification Decision

A class consisting of the Zyprexa Third-Party Payors—institutional plaintiffs such as pension funds, labor unions, and insurance companies that cover their members' health benefits—was certified in a case that is part of the Zyprexa MDL. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 201. Class members' claims are predicated on overpricing of Zyprexa as a result of Lilly's alleged improper promotional activity and disavowal of adverse side-effects. *See id.* at 78 ("It is alleged that . . . Lilly has withheld information and disseminated misinformation about the safety and efficacy of Zyprexa and has promoted and marketed the drug for uses for which it was not indicated . . . . As a result . . . Zyprexa commanded a higher price that it would have had the truth been known . . . .").

In the Third-Party Payors case, as in the present case, plaintiffs' claims depend for critical support on statistical evidence. The Third-Party Payors' evidence was found by the trial court to be sufficiently reliable and non-speculative to demonstrate that Zyprexa was overpriced, supporting a *Basic*-like presumption of reliance and avoiding the need for individualized proof. As a result, the Individualized Proof Rule was found inapplicable to the Third-Party Payors' claims.

a) Reliance

The Third-Party Payors certification decision noted *McLaughlin's* holding that "reliance on the misrepresentation [ ] cannot be the subject of general proof." 253 F.R.D. at 193 (quoting *McLaughlin,* 522 F.3d at 223). This court distinguished *McLaughlin* in part on the ground that

plaintiffs had presented sufficient evidence of overpricing, which was lacking in *McLaughlin*. *Id.* at 194.

The *McLaughlin* court had concluded that the need for individualized proof could not be avoided by arguing that all purchasers of light cigarettes had paid an inflated price, because there was insufficient evidence that the price of light cigarettes, which appeared to be unresponsive to relevant information, was actually inflated. *See* Part IV.E.1.b, *supra*; *McLaughlin*, 522 F.3d at 226 ("Indeed, the fact that the market did not shift away from light cigarettes after the publication of Monograph 13 is compelling evidence that plaintiffs had other, non-health related reasons for purchasing Lights."); *id.* The crucial difference in the Third-Party Payors case was that sufficient evidence suggested that the market for Zyprexa was responsive to the information regarding safety and efficacy that was allegedly misstated or suppressed by Lilly:

> The economic analyses undertaken in the instant case contain the features of reliability lacking in *McLaughlin*. For example, in *McLaughlin* there was a "lack of an appreciable drop in the demand . . . of light cigarettes after the truth about lights was revealed . . . ." Here, however, there is a remarkable decline in the demand for Zyprexa after only some of the truth was revealed, despite Lilly's attempts to ameliorate its effects. Unlike the tobacco companies in *McLaughlin*, here Lilly itself ascribed the diminution in demand for Zyprexa to the disclosures of the American Diabetes Association's consensus statement in late 2003 and early 2004. And the decline occurred before further key revelations—e.g., (i) the lack of comparative cost effectiveness of Zyprexa to perphenazine or other antipsychotics, as revealed in CATIE and later trials; (ii) the FDA's eventual acquisition of data (previously undisclosed by Lilly) leading up to the label change in October 2007; and (iii) analyses regarding the lack of efficacy and safety issues posed by treating elderly persons with dementia by prescribing Zyprexa.

253 F.R.D. at 190 (citation omitted). The fact that the Zyprexa market was responsive in terms of numbers of sales to such adverse information suggested that Zyprexa's price had been

inflated, supporting a *Basic*-style presumption of reliance. Since Lilly's patent gave it a monopoly, the circumstance that the price was not adversely affected was irrelevant. The trial court accordingly held that individualized proof of reliance was unnecessary, because *all* payors paid the allegedly inflated price for Zyprexa, regardless of what they knew:

> Unlike *McLaughlin,* here the evidence supports a finding of an overcharge based on the fraud on doctors, third-party payors, and others. The overcharge resulted in specific damages to the plaintiffs who overpaid for Zyprexa.
>
> *McLaughlin* found that "differences in plaintiffs' knowledge and levels of awareness also defeat the presumption of reliance" in cigarette cases. *Id.* at 226. Here the total fraud resulted in an increased price as in securities cases, so the fact that some doctors, patients or others were aware of the fraud is irrelevant. Without the fraud the price would have been lower to all payors.

253 F.R.D. at 194-95.

The Third-Party Payors trial court considered, but ultimately rejected, a proposal to treat off-label Zyprexa prescriptions differently from on-label prescriptions:

> A single price was charged for uses of the drug approved by the United States Food and Drug Administration ("FDA") ("on-label") and those not so approved ("off-label"). Subclassing for these two categories of drug use is proposed, but is denied. There is evidence that off-label use of Zyprexa was excessive and may have been encouraged by Lilly. See, e.g., Laurie Tarkan, Doctors Say Medication [Including Zyprexa] Is Overused in Dementia, N.Y. Times, June 24, 2008, at F1. A cause of action for Lilly's urging such off-label use may exist, but it is independent of the case as it is now being certified based solely on overcharging for use of Zyprexa in any form.

253 F.R.D. at 76 (alteration in original). The Third-Party Payors' claims were allowed by the trial court to proceed only on the basis of the difference between the actual value of Zyprexa to patients and a uniform, inflated price paid by all purchasers. Bound by *McLaughlin*, the court

refused to recognize a separate set of claims based on the further theory that certain class members, who would not have been prescribed Zyprexa but for Lilly's improper conduct, sustained injuries from Zyprexa that they otherwise might have avoided.

The trial court nonetheless left open the possibility that the Third-Party Payors might be able to recover different amounts for different subgroups of Zyprexa patients, based on the theory that patients who were given Zyprexa for unapproved uses received less benefit from Zyprexa, and therefore the difference for those patients between the market price of Zyprexa and the value received was greater than for other patients. Expert testimony estimating the value of Zyprexa for certain uses as low as zero was deemed appropriate for a jury trial. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 158-59, 165. For example Dr. Rosenthal's analysis in the Third-Party Payors case, as in the present case, proceeded on the assumption that any prescriptions that, as a matter of statistical analysis, appeared to have resulted from Lilly's improper promotional efforts would deliver zero value to the patient. *See* 253 F.R.D. at 159; Rogoff Aff., Ex. 34 ¶ 8 (assuming "the entire expenditure to be lost value (i.e. . . . a yardstick of zero dollars)" for "prescriptions that were caused by Lilly's alleged illegal promotion of Zyprexa for unapproved uses"). The trial court noted that although this theory was subject to various objections, "[t]he jury can accept much of this criticism as valid while giving substantial weight to [the expert's] analyses and damage estimates." 253 F.R.D. at 159.

b) Loss Causation

The Third-Party Payors opinion was compelled to afford full weight to *McLaughlin*'s holding that "the issue of loss causation, much like the issue of reliance, cannot be resolved by way of generalized proof." 253 F.R.D. at 195 (quoting *McLaughlin*, 522 F.3d at 226). As in the case of reliance, because the Third-Party Payors' evidence of overpricing was held to be

sufficient, the individualized loss-causation issues that were fatal in *McLaughlin* did not arise: "Proof in the instant case is not generalized. The plaintiffs were directly injured by Lilly when each was overcharged a fixed computable amount for each prescription." *Id.*

c) Injury

Like the *McLaughlin* plaintiffs, the Third-Party Payors offered expert testimony in support of "quantity effect" and "loss of value" statistical models of damages sustained by class members. *See* 253 F.R.D. at 158-66. The use of such models was found lacking and improperly speculative in *McLaughlin*. *See* 522 F.3d at 228-230. But the Third-Party Payors' statistical model was held by the trial court on the basis of its evidentiary *Daubert* hearing to be more robust and reliable than that offered by the *McLaughlin* plaintiffs:

> Contrary to the salient flaws found by the appellate court in the causation and damages model presented by the plaintiffs in *McLaughlin*, plaintiffs' Zyprexa model reflects actual overcharges and actual harm caused by defendant. A jury could find that [plaintiffs' experts'] calculations of aggregate damages for the class are sufficiently reliable and appropriate based on the record.

253 F.R.D. at 190. The trial court concluded that "plaintiffs have supported their theory of price impact sufficiently to go to a jury." *Id.* at 195.

3. Appeal of the Third-Party Payors Certification Decision

An appeal of the Third-Party Payors certification decision is pending before the Court of Appeals for the Second Circuit. *See In re Zyprexa Prods. Liab. Litig.*, No. 09-0222 (2d. Cir.) The Third-Party Payors court considered and distinguished the Individualized Proof Rule analysis in *McLaughlin, see* Part IV.E.1.b, *supra*, and the resulting certification decision is analytically consistent with *McLaughlin* and other cases that have applied the Individualized Proof Rule. None of the decisions of the Court of Appeals invoking the Individualized Proof

Rule or rejecting the use of statistical evidence directly controlled the outcome of the Third-Party Payors' certification motion.

Nevertheless, in light of the majority of the Courts of Appeals' hostility to the use of aggregate proof, as demonstrated in *McLaughlin* and other decisions, *see* Part IV.E.1, *supra*, there is some doubt concerning the appellate court's willingness to accept statistical evidence of the kind that is necessary to the success of the Third-Party Payors' claims.

V. Application of Law to Facts

Mississippi's claims are premised on Zyprexa prescriptions over more than a decade to tens of thousands of patients statewide. Its claims largely depend for their validity on generalized proof, in the form of expert analysis, relating to this population of Zyprexa patients in the aggregate. The Individualized Proof Rule, in general, bars the use of generalized or aggregate proof outside of the securities fraud context to establish reliance, loss causation, or injury. The Third-Party Payors certification decision found that the Individualized Proof Rule did not apply where aggregate proof was used to establish an inflated price and resulting damages. An inflated price is paid by, and is detrimental to, *all* market participants, regardless of their knowledge or individual circumstances, obviating the need for separate proof with respect to each individual participant. *See* Part IV.E.2, *supra*.

The Third-Party Payors' exception to the Individualized Proof Rule would apply to Mississippi's CPA, fraud, and negligence claims, insofar as they seek to recover the difference between the value received by Zyprexa patients and the market price of Zyprexa reimbursed by the State. These claims may survive summary judgment, subject to the outcome of the appellate court's review of the Third-Party Payors certification decision.

Through its PLA, CPA, fraud, and negligence claims, Mississippi seeks recovery of other damages, such as amounts paid to treat diseases caused by Zyprexa. These theories do not fall within the Third-Party Payors' exception to the Individualized Proof Rule. Because the State relies on aggregate proof to establish these claims, they are barred by the Individualized Proof Rule and cannot survive summary judgment.

Through its MFCA and unjust enrichment claims, Mississippi seeks to recover amounts paid and statutory penalties for each off-label or "non-medically necessary" Zyprexa prescription that resulted from Lilly's alleged misconduct. These claims are based, not on an alleged difference between Zyprexa's price and the value received, but on the theory that Lilly's misconduct resulted in medically unnecessary Zyprexa prescriptions that would not otherwise have been made. These claims do not fall within the Third-Party Payors' exception to the Individualized Proof Rule, and do not survive summary judgment.

Under its CPA, Mississippi seeks to recover a statutory penalty for every Zyprexa prescription ever written in Mississippi, in amounts to be determined in the court's sole discretion but "not to exceed" $10,000 for each prescription. *See* Part IV.C.3, *supra*. Exercising discretion in determining the proper amount of the fines that would attach to each of almost one million Zyprexa prescriptions, or—according to another measure proposed by plaintiff's expert Dr. Rosenthal—over one hundred thousand "episodes of care," *see* Rogoff Aff., Ex. 34 ¶¶ 22-23, would necessarily require individualized consideration of the circumstances of each case. Such an inquiry is administratively impossible, and beyond the capacity of the court. More importantly, the aggregate proof proffered by the State is insufficient to properly inform an

exercise of that nature. Dismissal of Mississippi's claim for CPA statutory penalties on summary judgment is appropriate.

A. PLA Claim

The State seeks through its PLA claim to recover the costs of treating illnesses caused by Zyprexa. *See* Am. Compl. ¶¶ 10.2-10.11; Pl.'s Response at 40-41 (asserting that the PLA claim is based on "physical injuries to a significant number of Mississippi citizens"). The economic loss rule limits liability under the PLA to physical injury to persons or property. *See* Part IV.C.2, *supra*; *see also State Farm Auto. Ins. Co. v. Ford Motor Co.*, 736 So. 2d 384, 388 (Miss. Ct. App. 1999); *Miss. Chem. Corp. v. Dresser-Rand Co.*, 287 F.3d 359, 364 n.3 (5th Cir. 2002). The variation in individual cases is so large that aggregate evidence offered in support of the PLA claim is inadequate under the Individualized Proof Rule. The claim does not survive summary judgment.

The PLA claim rests on the premise that Zyprexa was defective with respect to its warnings and was in breach of express warranties and representations of safety and efficacy. Am. Compl. ¶¶ 10.2-10.3. The State contends that adequate warnings "would have successfully influenced Mississippi health care providers . . . not to prescribe Zyprexa," and that the State "would not have . . . expended funds in providing necessary health care treatment and other necessary assistance to certain eligible Medicaid recipients who presently suffer, or have suffered, from Zyprexa-related injuries." *Id.* ¶ 10.6. The alleged defects are said to have "proximately caused, or proximately contributed to the cause, of the damages for which recovery is sought" under the PLA. *Id.* ¶ 10.8.

This theory is unrelated to the overpricing theory endorsed in the Third-Party Payors case. It does not reference the difference between Zyprexa's price and the value received by patients. Rather, the claim is that patients sustained physical injuries they would not have but for Lilly's alleged promotional misconduct. There is no market mechanism, such as price inflation, at work which intervenes in the causal chain to render individualized proof of reliance or loss causation unnecessary. The Third-Party Payors' exception to the Individualized Proof Rule does not apply. For this claim to succeed, it must be shown that Mississippi physicians *relied* uniformly on Lilly's warnings and express warranties and representations in prescribing Zyprexa, which *resulted in* metabolic diseases for which the State paid the costs of treatment. *See* Part IV.C.2, *supra*; Miss. Code Ann. § 11-1-63(a)(ii). The Individualized Proof Rule instructs that "reliance . . . cannot be the subject of general proof," *McLaughlin*, 522 F.3d at 223, and that "loss causation . . . cannot be resolved by way of generalized proof," *Id.* at 226.

In *McLaughlin*, "[i]ndividualized proof [was] needed to overcome the possibility that a member of the purported class purchased Lights for some reason other than the belief that Lights were a healthier alternative." *Id.* at 223 Individualized proof is needed in the instant case to overcome the possibility that a Mississippi patient was prescribed Zyprexa for some reason other than belief in the accuracy of Lilly's warnings or representations. Whether a more adequate warning by Lilly would have prevented any particular patient's injuries requires consideration of what the prescribing physician knew and the cost-benefit analysis that applied to the individual patient suffering from a variety of serious mental problems observed by the physician to be affected by the drug to varying degrees. The same analysis requires individualized proof of loss causation. Each individual patient's metabolic condition would have to be shown to have

resulted from Zyprexa, rather than other supervening causal factors. Any damages would similarly have to be calculated on an individualized basis.

Instead of individualized proof for these purposes, Mississippi offers generalized expert analyses. Offered are the expert opinions of Dr. Abramson and Dr. Rosenthal to establish that prescribing physicians relied on Lilly's warnings and representations. Dr. Abramson concludes that Lilly's alleged misconduct would have "had a substantial effect on the prescribing behavior of doctors and the willingness of the health care market to pay for Zyprexa," and that "Lilly's exploitation of various sources from which doctors derive prescription drug information . . . would have served to increase the quantity of prescriptions written for Zyprexa." Rogoff Aff., Ex. 36 at 1; *see* Part III.G.3, *supra*. Dr. Rosenthal estimates "the number of prescriptions that were caused by Lilly's allegedly illegal promotion of Zyprexa for unapproved uses." Rogoff Aff., Ex. 34 ¶ 8; *see* Part III.G.3, *supra*. Both Dr. Abramson and Dr. Rosenthal analyze these effects across the entire population of Zyprexa patients. Under the Individualized Proof Rule, neither expert's resulting conclusions may be used to establish reliance.

Similarly, to show loss causation Dr. Rosenthal estimates that Zyprexa caused $2,736,798 per year in diabetes-related costs in Mississippi. *See* Rogoff Aff., Ex. 34 ¶ 32. That calculation is based on the average rate at which Zyprexa use causes diabetes, the number of Mississippi patients who were prescribed Zyprexa, and the average incremental costs of medical care caused by diabetes. Rogoff Aff., Ex. 34 ¶ 32; *see* Part III.G.2, *supra*. But as Dr. Rosenthal notes, "[t]he data used for this calculation may not account for all the dynamics of treatment changes and disease progression that could affect outcomes for individual patients." *Id.* ¶ 33. This generalized statistical evidence is insufficient under the Individualized Proof Rule.

In order for the State to recover damages under its PLA theory, each prescribing decision and each patient's injuries would have to be considered individually. The many summary judgment motions already decided by the court, *see* Part II.B, *supra*, demonstrate that each case is fact-specific, making categorization almost impossible. In the absence of such individualized showings, the PLA claim cannot survive summary judgment.

B. MFCA and Unjust Enrichment Claims

The State asserts two bases for its MFCA claim. It contends, first, that "Zyprexa prescriptions *that resulted from Lilly's affirmative and consistent failure to warn* that Zyprexa causes" weight gain and diabetes "were fraudulent claims." Pl.'s Response at 45 (emphasis added). Second, it asserts that "Zyprexa prescriptions *for non-medically necessary uses* were false claims because they were excluded from payment under Mississippi Medicaid." Pl.'s Response at 45 (emphasis added); *see also* Am. Compl. ¶¶ 9.2, 9.4.

The State's unjust enrichment theory is related to the second MFCA theory. It is asserted that Lilly has been "unjustly enriched" and has "unjustly benefited" as a result of its "unlawful and/or wrongful collection of . . . payments of funds by the State of Mississippi through its Division of Medicaid in purchasing Zyprexa *for non-medically necessary uses*." Am. Compl. ¶¶ 13.2-13.3 (emphasis added).

The State's aggregate evidence in support of these theories is insufficient. They cannot survive summary judgment.

1. Zyprexa Prescriptions Resulting from Lilly's Failure to Warn

The State's first MFCA theory is that "Zyprexa prescriptions *that resulted from Lilly's affirmative and consistent failure to warn* that Zyprexa causes" weight gain and diabetes "were fraudulent claims." Pl.'s Response at 45 (emphasis added). Like the State's PLA theory, this

theory is not premised on the difference between Zyprexa's price and the value received. Rather, the claim is that fraudulent Medicaid claims were made that would not have been but for Lilly's alleged misconduct. The Third-Party Payors' exception to the Individualized Proof Rule does not apply. For this claim to succeed, it must be shown how fraudulent claims resulted from, presumably, the reliance of prescribing physicians' on the absence of proper warnings. The case law instructs that "reliance . . . cannot be the subject of general proof." *McLaughlin*, 522 F.3d at 223.

The State offers no individualized proof. Instead, Dr. Abramson and Dr. Rosenthal provide their expert opinions, tending to show that, *in general*, Lilly's alleged misconduct would have resulted in additional Zyprexa prescriptions. *See* Part III.G.3, *supra.* Dr. Abramson's and Dr. Rosenthal's analyses on this point consist of aggregate proof of the kind barred by the Individualized Proof Rule for purposes of showing reliance. *See* Part IV.E.1, *supra.* This MFCA theory cannot survive summary judgment.

2. "Non-Medically Necessary" Zyprexa Prescriptions

Mississippi's second MFCA theory is that "Zyprexa prescriptions *for non-medically necessary uses* were false claims because they were excluded from payment under Mississippi Medicaid." Pl.'s Response at 45 (emphasis added); *see also* Am. Compl. ¶¶ 9.2, 9.4. The State's unjust enrichment claim is also based upon the Medicaid program's purchases of Zyprexa for "non-medically necessary" uses. *See* Am. Compl. ¶¶ 13.2-13.3. Assuming that the State is correct in its view that its Medicaid program is only required to reimburse for "medically necessary" uses of Zyprexa, *see* Part III.F, *supra*, these claims nevertheless cannot survive summary judgment.

This theory is premised not on the difference between Zyprexa's price and the value actually received, but rather on the concept of "medical necessity." The Mississippi Division of Medicaid's definition of "medically necessity" incorporates seven complex factors, including whether failure to provide a given treatment is "appropriate and consistent with the diagnosis of the treating provider and the omission of which could adversely affect the patient's medical condition," whether the treatment is "compatible with the standards of acceptable medical practice in the United States," whether the treatment is "provided in a safe, appropriate and cost-effective setting given the nature of the diagnosis and the severity of the symptoms," and whether there is any "other effective and more conservative or substantially less costly treatment . . . available." *See* Part III.F, *supra*; Rogoff Aff., Ex. 1 at § 53.22 (Division of Medicaid, Provider Policy Manual, Jan. 1, 2006).

Several of the criteria for "medical necessity" are context-sensitive, rather than one-size-fits-all. Because each patient presents a unique set of symptoms and indications, and each patient may respond differently to any given medication, it requires a highly specific, individual analysis to determine, for example, whether there exists for a given patient another "effective and more conservative or substantially less costly treatment." "Due to the illnesses' heterogeneity, different people respond differently to different psychotropic drugs. Which drug will work best for a new patient is often unknown until he or she tries it; thus clinical decision-making about psychotropic medications almost inevitably is based on 'trial and error.'" *In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 98-99.

Whether a prescription of Zyprexa, or any medical intervention, is "medically necessary" must take into account all the information available to the prescribing physician about the risks

and benefits with respect to the individual patient in question and the myriad vectors affecting the presenting person, his family, and his associates. Whether, for example, to risk weight gain to effect relief from dreadful mental disease to obtain a livable lifestyle, requires exquisitely balanced judgment of the prescribing physician. The concept of "medical necessity" therefore does not operate in a mechanical way, as the concept of price inflation did in the Third-Party Payors case, to render individualized proof of reliance or loss causation unnecessary.

"Medical necessity," as a term of art under defined by the Mississippi Medicaid program, does not fall within the categories of reliance, loss causation, or injury—the three elements generally subject to the Individualized Proof Rule. Nonetheless, because of the necessarily individualized nature of the determination of medical necessity, the Individualized Proof Rule applies. In *McLaughlin,* "[i]ndividualized proof [was] needed to overcome the possibility that a member of the purported class purchased Lights for some reason other than the belief that Lights were a healthier alternative." 522 F.3d at 223. For purposes of Mississippi's MFCA and unjust enrichment claims, individualized proof is required to overcome the possibility that Zyprexa was prescribed for a valid, medically necessary reason, despite any influence exerted by Lilly's alleged promotional misconduct.

Mississippi offers no individualized proof on the issue of medical necessity. It is asserted that "there were substantially less costly and equally effective treatments available for non-medically necessary uses, which precludes Zyprexa from qualifying as 'medically necessary' under the [Division of Medicaid's] definition of that term." Pl.'s Response to Def.'s Statement of Undisputed Material Facts, Oct. 20, 2009, ¶ 60. The State's papers do not identify the evidence offered to establish this allegation, but support would appear to come (again) from the

opinions of Dr. Abramson and Dr. Rosenthal regarding the extent to which Lilly's alleged misconduct may have increased the number of Zyprexa prescriptions. *See* Parts III.G.3, *supra*. The State may also rely on Dr. Abramson's view that Lilly knowingly made claims of Zyprexa's safety and cost-effectiveness that were unsupported by available evidence. *See id.*; Rogoff Aff., Ex. 36 ¶¶ 191-92 (Expert Rep. of John Abramson). Other experts may be offered by the State to attack the safety, cost-effectiveness, and efficacy of Zyprexa. *See* Pl.'s Br. at 22 (listing Drs. Rosenbeck, Harris, Schneider, and Wirshing as additional experts for the State).

No such expert analysis has been sufficiently individualized. These conclusions are contrary to the evidence already analyzed in many Zyprexa cases. In particular, neither Dr. Abramson's generalization regarding the "substantial effect on . . . prescribing behavior" of Lilly's alleged conduct, nor Dr. Rosenthal's statistical estimate of "the number of prescriptions that were caused by Lilly's allegedly illegal promotion of Zyprexa for unapproved uses," addresses the medical necessity of Zyprexa on an individual basis. *See* Part III.G.3, *supra*. Any attacks other experts may make on Zyprexa's general efficacy or cost effectiveness would be insufficient as aggregate proof.

C. CPA Violations

Mississippi seeks both damages and civil penalties under its CPA. *See* Part IV.C.3, *supra*. The claim for damages under the CPA may survive summary judgment, at least in part. Summary judgment of dismissal is appropriate with respect to the claim for statutory penalties.

1. CPA Claim for Damages

Violators of the CPA are subject to liability in damages for "any ascertainable loss of money or property, real or personal, as a result of . . . a [prohibited] method, act or practice." *See* Part IV.C.3, *supra*; Miss. Code Ann. § 75-24-15(1). It is not evident from the State's papers or

oral arguments precisely what damages are sought in connection with the CPA claim. The State offers no separate evidence in support of its CPA claims, distinct from the generalized expert analyses previously discussed. No individualized evidence is offered.

For reasons already stated, *see* Parts V.A-B, *supra*, the claim for damages under the CPA may survive summary judgment to the extent that it is premised on the difference between Zyprexa's market price and the value actually received by patients, based upon theories and forms of aggregate evidence similar to those approved in the Third-Party Payors certification decision. Claims for damages based on different theories, such as the costs of treating illnesses resulting from Zyprexa, *see* Part IV.A, *supra*, or costs of purchases of Zyprexa for non-medically necessary uses, *see* Part IV.B.2, *supra*, cannot be established by the aggregate evidence offered. To the extent the State pursues such theories through its CPA claim, summary judgment of dismissal is appropriate.

2. CPA Claim for Statutory Penalties

The CPA provides for "a civil penalty in a sum *not to exceed* Ten Thousand Dollars ($10,000.00)" for each knowing and willful violation. Miss. Code § 75-24-19(1)(b) (emphasis added). Mississippi argues that this CPA provision is "triggered merely by Lilly's misrepresentations" of Zyprexa's characteristics or benefits, so that "proof of reliance or causation" is not required. Pl.'s Response at 29. Because the penalty is said to apply regardless of any costs or damages borne by the State, Mississippi requests a penalty to be assessed for each of almost a million estimated Zyprexa prescriptions in Mississippi. *See* Oct. 21, 2009 Hr'g Tr. at 14-15; Part IV.C.3, *supra.*

The statutory language indicates that the enforcing court is invested with discretion to determine the appropriate amount of the penalty with respect to each violation, whether the

maximum of $10,000 or some smaller amount. *See* Oct. 21, 2009 Hr'g Tr. at 15-16 (statement of Mississippi's counsel) ("It would be up to the court. The judge makes the determination as to whether the [CPA] was violated, how many times, and the appropriate penalty [ ] in light of the evidence.") The statute does not specify what factors are to inform the court's determination, but in the present case the court may wish to consider a number of issues as they bear on each Zyprexa prescription, including but not limited to: whether the prescription was for an on-label or off-label use; whether the prescription was medically necessary; whether the patient received any benefit from Zyprexa; whether and the extent to which the patient experienced any of Zyprexa's potential metabolic side effects; the information about Zyprexa available to the medical community at the time the prescription was written; and the times of the various alleged instances of misconduct by Lilly, and whether and to what extent each instance may have impacted the prescription in question.

Due to the nature of the alleged misconduct and injuries in the instant case, and in light of the discretion invested in the court to set the amount of the CPA penalty, proper assessment of the claimed penalties would require individualized consideration of the circumstances of each prescription alleged to be in violation of the statute. As previously pointed out, Mississippi has generally offered only aggregate evidence in support of its claims. It has not offered the kind of individualized information relating to each prescription that is needed to enable the requisite inquiry by the court in imposing discretionary penalties.

Regardless of the lack of individualized evidence, imposition of civil penalties on a per-violation basis would entail separate examination of each of hundreds of thousands of claimed violations for purposes of determining the appropriate fine. Such an inquiry is impractical and

beyond the resources of any court. Summary judgment is appropriate with respect to Mississippi's claim for statutory penalties under the CPA.

D. Common-Law Fraud and Negligence Claims

Mississippi's fraud and negligence claims both require a showing of causation by reliance of prescribing physicians. *See* Part IV.4, *supra.* These claims are subject to the same analysis as the State's other claims. They may survive summary judgment in part, based on theories and evidence similar to those approved in the Third-Party Payors decision. To the extent that they rely on other theories, they cannot survive summary judgment.

The fraud and negligence claims are each premised on a broad collection of overlapping allegations concerning Lilly's alleged misconduct. As a basis for fraud, it is alleged: that Lilly promoted Zyprexa "for non-medically necessary uses," Am. Compl. ¶ 12.2-12.3; that it implemented a marketing plan that "included evaluation of sales opportunities . . . based upon 'off-label' uses," *id.* ¶ 12.4; that it trained its sales force to convince physicians to prescribe Zyprexa for "mood, thought, and behavioral disturbances," and based on "symptoms and behaviors" rather than diagnoses, *id.*; that it used "patient profiles" to market Zyprexa for certain symptoms, *id.*; that it misrepresented Zyprexa's safety and efficacy, *id.*; that it failed to warn of adverse side effects, *id.* ¶ 12.6; and that it suppressed negative information about Zyprexa internally and trained its sales force to hide such information, *id.* ¶ 12.7.

As a basis for negligence and gross negligence, it is alleged: that Lilly failed to provide adequate warnings, *id.* ¶ 14.4; that it misrepresented Zyprexa's characteristics, benefits, and overall quality, *id.*; that it promoted Zyprexa for "non-medically necessary" uses, *id.*; that it failed to warn of adverse side effects, *id.*; that it suppressed or concealed material information

about safety and efficacy, *id.*; and that it failed to take due care in the "research, design, development, manufacture, testing, marketing, packaging, labeling, promotion, advertising, sale and distribution of Zyprexa," *id.*

All of the theories advanced under both claims have in common that they require a showing of reliance on Lilly's acts or omissions across the heterogeneous population of Mississippi patients and prescribing physicians, either in deciding to purchase Zyprexa at the market price, or in deciding to administer Zyprexa at all. They are subject to the Individualized Proof Rule regarding proof of reliance by aggregate evidence. The State offers no separate evidence in support of its fraud and negligence claims distinct from the generalized expert analyses previously discussed. No individualized evidence is offered.

It is not clear from the State's papers precisely what damages are sought in connection with its fraud and negligence claims. For reasons already stated, *see* Parts V.A-C, *supra*, the fraud and negligence claims may survive summary judgment to the extent they are premised on the difference between Zyprexa's market price and the value actually received by patients, based upon theories and forms of aggregate evidence similar to those approved in the Third-Party Payors certification decision. Claims for damages based on different theories, such as the costs of treating illnesses resulting from Zyprexa, *see* Part V.A, *supra*, or costs of purchases of Zyprexa for non-medically necessary uses, *see* Part V.B.2, *supra*, cannot be established by the aggregate evidence offered. To the extent the State pursues such theories through its fraud and negligence claims, summary judgment of dismissal is appropriate.

E. Pending Third-Party Payors Appeal and Stay of Proceedings

Mississippi's claims may survive summary judgment only to the extent that they are premised on the difference between Zyprexa's market price and the value actually received by

patients, based upon theories and forms of aggregate evidence similar to those approved in the Third-Party Payors certification decision. Mississippi relies on substantially identical expert analyses by several of the same experts used by the Third-Party Payors. *See* Parts III.G.1 & 3, *supra.*

An appeal of the Third-Party Payors certification decision is pending before the Court of Appeals for the Second Circuit. There is some doubt in that case about the appellate court's willingness to accept aggregate proof of the kind Mississippi will need to establish its claims based on hundreds of thousands of statewide Zyprexa prescriptions over the course of a decade. *See* Part IV.E.3, *supra.* Thus, there is little point in allowing the present litigation to proceed while review of a pivotal issue is pending and the result is in doubt. Decision on Lilly's summary judgment motion is therefore reserved on this aspect of Mississippi's claims. It is appropriate to stay these proceedings until the pending appeal of the Third-Party Payors certification decision is resolved.

VI. Other Considerations

A. Mississippi's Awareness of Risks and Benefits

Lilly argues that the State of Mississippi has "long been aware that its physicians prescribe Zyprexa for off-label uses," on the basis of deposition testimony by a State Department of Medicaid administrator and by psychiatrists employed by facilities operated by the State Department of Mental Health. Def.'s Memo. at 8-10 (citing deposition testimony). It is further implied that the State knew or should have known about Zyprexa's metabolic side-effects, because "the national medical community has known of Zyprexa's risks for years." *Id.* at 14-16. Evidence available from other litigations offers some support for the latter position, suggesting

that members of the Mississippi medical community have been aware of the metabolic side-effects of Zyprexa at least since March 2004, and perhaps earlier. *See* Part III.E.4, *supra.*

The State disputes Lilly's arguments, contending that "[t]hat evidence does not indicate that the State was aware of the widespread off-label use of Zyprexa in Mississippi, especially in light of the fact that a patient's medical history and diagnosis are not considered in the prior authorization process" for claims to Medicaid reimbursement for prescription drugs. Pl.'s Response at 6. The State also argues that "Lilly has not established that Mississippi's agencies have ever known the truth about Zyprexa's risks, let alone that they have long been aware of Zyprexa's true risks." *Id.* at 8.

A recent decision of the Alabama Supreme Court is said to provide support for Lilly's arguments opposing the State's claims. *See AstraZeneca LP v. State of Alabama*, --- So. 2d ---, Nos. 1071439, 1071440, 1071704, 1071759, 2009 WL 3335904 (Ala. Oct. 16, 2009); *see also* Notice of Supplemental Authority in Further Supp. of Def.'s Mot. for Summ. J., Nov. 6, 2009. The State of Alabama sued pharmaceutical manufacturers for fraudulently misrepresenting the prices of their drugs for the purpose of increasing the reimbursements they received from the Alabama Medicaid Agency ("AMA"). *AstraZeneca*, 2009 WL 3335904 at *1, 8. On appeal of a judgment in favor of the State, the defendants argued that Alabama could not establish reliance on the misrepresentations, because "the industry—and the AMA in particular—was at all relevant times *fully cognizant* of the fact that the manufacturer's published drug prices were list prices, which excluded discounts." *Id.* at *11 (original emphasis).

The Alabama Supreme Court agreed:

> The *sine qua non* of the State's fraud claims in these appeals is its assertion that it did not know that the published WACs and AWPs

> were merely suggested-or list-prices, exclusive of discounts and other incentives available to wholesalers and providers. This assertion is untenable in light of the correspondence and internal memoranda involved in the State's formulation of its reimbursement methodology.

Id. at * 13. The court concluded that, "given the State's particularized knowledge of the challenged reporting practices, a claim of common-law fraud—with its element of reasonable reliance—is, like the proverbial 'square peg in a round hole,' particularly ill-suited for the task to which it was put in this dispute." *Id.* at 16.

The reasoning of the *AstraZeneca* court is contended to apply to the present case, because "the un-contradicted record demonstrates that the State of Mississippi[,] its agencies, and its prescribing physicians knew of the alleged risks of Zyprexa before the 2003 label change, despite the State's claim that Lilly fraudulently misrepresented Zyprexa's risks." Notice of Supplemental Authority in Further Supp. of Def.'s Mot. for Summ. J. 3, Nov. 6, 2009. The court's summary judgment decision does not rely on this argument. Nevertheless, it has some cogency, particularly in the light of the fact that Zyprexa continues to be approved and paid for by the State even after filing its claims for fraud and lack of efficacy. *See, e.g.*, Rogoff Aff., Ex. 41 (Division of Medicaid DUR Board Meeting, May 15, 2008) (discussing off-label Zyprexa prescriptions to teenagers for the period from Feb. 23, 2007 to Feb. 22, 2008).

Whether or for how long the State has actually been aware of Lilly's allegedly improper conduct or the truth about Zyprexa, the State's role and responsibilities with respect to a widely prescribed medication like Zyprexa are worthy of consideration. The State of Mississippi, unlike the Third-Party Payors, has obligations to taxpayers, a huge administration and supervisory bureaucracy, and contact with the medical and health professionals who administer and are

employed by its Medicaid program. The State has a special opportunity, and, arguably, a special obligation to understand the benefits and dangers of widely prescribed drugs, including their appropriate off-label uses and potential adverse side effects, in order to effectively administer State programs and manage government expenditures.

B. Social Value of Zyprexa

The social value of the product at issue in this litigation is also noteworthy. The Court of Appeals for the Second Circuit has been reluctant in tobacco litigations to permit causes of action predicated on cigarette use by many people. *See* Part IV.E.1.b, *supra.* The tobacco cases involved the production, merchandizing, and promotion of an admittedly deleterious product that has devastated the health of millions. Lilly, in contrast, has created a product with substantial benefits that even now—after many years of litigation, research, testing, and controversy—is still favored by many physicians and patients in Mississippi and elsewhere for some of the most serious psychological conditions that afflict millions of people worldwide. Courts cannot ignore the substantial benefits accruing to the State of Mississippi and its citizens from the use of Zyprexa. The State arguably saved large sums through use of Zyprexa by preventing users with serious mental problems from requiring hospitalization in State facilities, and allowing them to become productive taxpayers and participants in the economy. *Cf.* Andrew Longstreth, "Summary Judgment Motion Knocks Out Texas AG's Vioxx Suit," The Am Law Litigation Daily, Nov. 23, 2009, *available at* http://www.law.com/jsp/tal/digestTAL.jsp?id=1202435771957&Summary_Judgment_Motion_Knocks_Out_Texas_AGs_Vioxx_Suit (reporting Texas state court's dismissal of Texas Attorney General's Medicaid fraud action against Merck concerning its painkiller Vioxx; Merck's motion argued that that "[t]his lawsuit is

an effort by the state of Texas to obtain a windfall: to recoup money it spent covering a prescription drug for Medicaid beneficiaries even though it does not claim that the drug injured them or that it failed to work (and even though it cannot prove that alternative drugs would have been cheaper).").

C. Unconstitutional Punitive Aspects

In its punitive aspects, serious constitutional and other questions about the utilization of the structural class action for punitive purposes are implicated. The scale of the potential recovery sought by Mississippi may implicate the constitutional limitations on excessive fines and punitive damages.

The Eighth Amendment to the Constitution prohibits the imposition of "excessive fines." Through the Due Process Clause of the Fourteenth Amendment, the Excessive Fines clause is applicable to the states as well as the federal government. *Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 433-34 (2001). "The Due Process Clause of its own force also prohibits the States from imposing 'grossly excessive' punishments on tortfeasors." *Id.* at 434. The same limitations apply to awards of punitive damages in civil litigation. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003). The reason for these limitations is that "'[e]lementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose.'" *Id.* at 417 (quoting *BMW of North America, Inc. v. Gore,* 517 U.S. 559, 574 (1996)).

Whether a penalty is constitutionally excessive is determined by considering "the degree of the defendant's responsibility or culpability; . . . the relationship between the penalty and the

harm to the victim . . . , and the sanctions imposed in other cases for comparable misconduct." *Cooper Indus.*, 532 U.S. at 435; *see also State Farm*, 538 U.S. at 418; *United States v. Bajakajian*, 524 U.S. 321, 334-41 (1998) (finding civil forfeiture of $357,144 in currency would be grossly disproportionate and constitutionally excessive where the only offense was failure to report the currency when attempting to leave the United States with it for an otherwise lawful purpose).

Under this constitutional fairness and equity standard, Mississippi's requests for statutory penalties on a per-violation basis, in addition to actual damages sought, would result in a multi-billion dollar cumulative penalty grossly disproportionate to both the injury Mississippi has suffered and the seriousness of Lilly's alleged misconduct. *Cf. United States v. Bickel*, No. 02-3144, 2006 WL 1120439, *3 (C.D. Ill. Feb. 22, 2006) ("Bickel submitted 32,949 false claims, and the United States suffered actual damages of $184,422.13. . . . The minimum statutory civil penalty would total $181,219,500.00 ($5,500.00 for each of the 32,949 false claim[s] submitted). The United States, however, only seeks civil penalties of $11,000.00. The United States takes the position that the full statutory civil penalty would violate the Excessive Fines Clause."); *cf. In re Simon II Litig.*, 407 F.3d 125 (2d Cir. 2005) (refusing to certify class seeking punitive damages from tobacco companies). As Coffee and Wolf put the matter in their comprehensive review of current class action law:

> In cases involving immense potential statutory damages for defendants coupled with virtually no harm to plaintiffs, some courts have invoked superiority to defeat certification. In a number of cases under the Fair and Accurate Credit Transactions Act ("FACTA"), courts in the Eleventh and Ninth Circuits have relied on superiority to deny certification. *See, e.g., Leysoto v. Mama Mia I., Inc.*, 255 F.R.D. 693, 698 (S.D. Fla. 2009); *Saulic v. Symantec Corp.*, 596 F. Supp. 2d 1323, 1328 (C.D. Cal. 2009).

> FACTA, which regulates the information businesses may print on consumers' credit card receipts, includes statutory damages for various violations of the act. When businesses include too much information on customer receipts, then can become subject to statutory damages for countless defendants, even though the offending receipts have not caused any harm. To prevent crippling liability, some courts have refused to certify the classes.")

Coffee & Wolf, *supra*, at S-35.

If allowed to proceed in their entirety, the State's claims could result in serious harm or bankruptcy for this defendant and the pharmaceutical industry generally. *Cf.* Harold L. Korn, Arthur R. Miller, *et. al.*, *New York Civil Practice* ¶ 901.22 (first ed., 1997) (noting that New York CPLR 901(b), which "prohibits the maintenance of a class action to recover a penalty . . . unless the statute creating or imposing such remedy specifically [so] authorizes," "would presumably *protect businesses against catastrophic judgments*" (emphasis added)).

For the legal system to be used for this slash-and-burn-style of litigation would arguably constitute an abuse of the legal process. Constitutional, statutory, and common law rights of those injured to seek relief from the courts must be recognized. But courts cannot be used as an engine of an industry's destruction.

VII. Mississippi's Motion for Partial Summary Judgment

Mississippi moves for summary judgment as to liability on its CPA and unjust enrichment claims for the period from September 1, 1999 through March 31, 2001. The motion is based upon Lilly's having pleaded guilty in the federal district court for the Eastern District of Pennsylvania to a misdemeanor count under a strict liability "misbranding" statute. *See* 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1). The guilty plea did not admit any facts relating to

Mississippi, or physicians who treated Mississippi Medicaid recipients. No dispositive evidence was offered on the elements of Mississippi's state law claims.

The State of Mississippi's motion for partial summary judgment is denied. The defenses raised by Lilly to the State's motion for partial summary judgment are not relevant and need not be considered at this time.

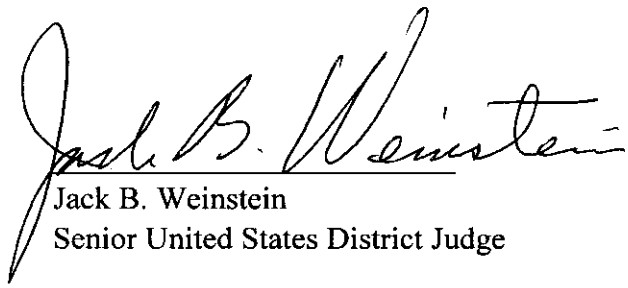
VIII. Conclusion

Lilly's motion for summary judgment is granted except that decision is reserved on Mississippi's claims based on the difference between Zyprexa's market price and the value actually received, an issue now before the Court of Appeals for the Second Circuit.

Mississippi's motion for partial summary judgment is denied.

This order and partial summary judgment is not certified for interlocutory appeal since such an immediate appeal would not materially advance the ultimate termination of the litigation. *See* 28 U.S.C. § 1292(b). Proceedings in this action are stayed pending disposition of the appeal of the Third-Party Payors certification decision. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69 (E.D.N.Y. 2008), *appeal pending*, No. 09-0222 (2d Cir.).

SO ORDERED.



Jack B. Weinstein
Senior United States District Judge

Date: December 1, 2009
Brooklyn, New York